

**Clinical trial results:****Dapagliflozin Effect on Cardiovascular Events A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Dapagliflozin 10 mg Once Daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Ischemic Stroke in Patients with Type 2 Diabetes****Summary**

EudraCT number	2013-000239-28
Trial protocol	GB CZ IT SE SK BG NL ES DE PL HU BE
Global end of trial date	16 September 2018

**Results information**

Result version number	v1 (current)
This version publication date	25 September 2019
First version publication date	25 September 2019

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

Sponsor protocol code	D1693C00001
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01730534
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	151 85, Södertälje, Sweden,
Public contact	Information Centre, AstraZeneca AB, +1 800 2369933, information.centre@astrazeneca.com
Scientific contact	Global Study Leader, AstraZeneca, +49 4103 708 3792, Sandra.ranft@astrazeneca.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	11 September 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 September 2018
Global end of trial reached?	Yes
Global end of trial date	16 September 2018
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective is to determine the effect of dapagliflozin relative to placebo on cardiovascular outcome when added to current background therapy in patients with type 2 diabetes mellitus (T2DM) with either established cardiovascular disease or at least two cardiovascular risk factors.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 April 2013
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	Brazil: 326
Country: Number of subjects enrolled	Mexico: 868
Country: Number of subjects enrolled	Australia: 414
Country: Number of subjects enrolled	China: 215
Country: Number of subjects enrolled	Hong Kong: 50
Country: Number of subjects enrolled	India: 193
Country: Number of subjects enrolled	Japan: 95
Country: Number of subjects enrolled	Philippines: 336
Country: Number of subjects enrolled	Korea, Republic of: 357
Country: Number of subjects enrolled	Taiwan: 110
Country: Number of subjects enrolled	Argentina: 683
Country: Number of subjects enrolled	Thailand: 259
Country: Number of subjects enrolled	Vietnam: 157
Country: Number of subjects enrolled	Belgium: 114
Country: Number of subjects enrolled	Bulgaria: 832
Country: Number of subjects enrolled	Czech Republic: 638
Country: Number of subjects enrolled	France: 187
Country: Number of subjects enrolled	Germany: 215
Country: Number of subjects enrolled	Hungary: 713
Country: Number of subjects enrolled	Israel: 340
Country: Number of subjects enrolled	Italy: 155

Country: Number of subjects enrolled	Netherlands: 401
Country: Number of subjects enrolled	Poland: 931
Country: Number of subjects enrolled	Romania: 483
Country: Number of subjects enrolled	Russian Federation: 395
Country: Number of subjects enrolled	Slovakia: 346
Country: Number of subjects enrolled	South Africa: 456
Country: Number of subjects enrolled	Spain: 195
Country: Number of subjects enrolled	Sweden: 453
Country: Number of subjects enrolled	Turkey: 53
Country: Number of subjects enrolled	Ukraine: 356
Country: Number of subjects enrolled	United Kingdom: 366
Country: Number of subjects enrolled	Canada: 1583
Country: Number of subjects enrolled	United States: 3885
Worldwide total number of subjects	17160
EEA total number of subjects	6029

Notes:

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### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	9253
From 65 to 84 years	7890
85 years and over	17

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

In DECLARE at the first visit, i.e. the enrollment visit 1, patients were evaluated regarding the protocol mandated inclusion and exclusion criteria. If eligible, the patient started a single-blind (for the patient) run-in period receiving placebo tablets for 4-8 weeks.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Dapa 10 mg

Arm description:

Dapagliflozin 10 mg tablets administered orally once daily

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

Dosage and administration details:

Dapagliflozin 10 mg tablets administered orally once daily

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

Matching placebo for dapagliflozin 10 mg administered orally once daily

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:

Matching placebo for dapagliflozin 10 mg administered orally once daily

<b>Number of subjects in period 1</b>	Dapa 10 mg	Placebo
Started	8582	8578
Completed	8473	8433
Not completed	109	145
Consent withdrawn by subject	97	127
Lost to follow-up	12	18

## Baseline characteristics

### Reporting groups

Reporting group title	Dapa 10 mg
Reporting group description: Dapagliflozin 10 mg tablets administered orally once daily	
Reporting group title	Placebo
Reporting group description: Matching placebo for dapagliflozin 10 mg administered orally once daily	

Reporting group values	Dapa 10 mg	Placebo	Total
Number of subjects	8582	8578	17160
Age, Customized Units: Subjects			
<65 years	4631	4622	9253
>=65 years	3951	3956	7907
Age Continuous Units: years			
arithmetic mean	63.9	64.0	
standard deviation	± 6.8	± 6.8	-
Sex: Female, Male Units: Subjects			
Male	5411	5327	10738
Female	3171	3251	6422
Race/Ethnicity, Customized Units: Subjects			
White	6843	6810	13653
Black or African American	295	308	603
Asian	1148	1155	2303
American Indian or Alaska Native	52	52	104
Native Hawaiian or other Pacific Islander	9	13	22
Other	235	240	475
Age, Customized Units: Subjects			
<75 years	8044	8020	16064
>=75 years	538	558	1096
Baseline CV risk category Units: Subjects			
Established CV disease	3474	3500	6974
Multiple risk factors for CV events	5108	5078	10186
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1298	1270	2568
Not Hispanic or Latino	7284	7308	14592
Unknown or Not Reported	0	0	0

## End points

### End points reporting groups

Reporting group title	Dapa 10 mg
Reporting group description:	Dapagliflozin 10 mg tablets administered orally once daily
Reporting group title	Placebo
Reporting group description:	Matching placebo for dapagliflozin 10 mg administered orally once daily

### Primary: Time to first event included in the composite endpoint of CV death, MI or ischemic stroke

End point title	Time to first event included in the composite endpoint of CV death, MI or ischemic stroke
End point description:	Safety and co-primary efficacy
End point type	Primary
End point timeframe:	up to 5.2 years

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8582	8578		
Units: Participants				
Number of patients with an event	756	803		

### Statistical analyses

Statistical analysis title	Cox regression
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	17160
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.172
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.03

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**Primary: Time to first event included in the composite endpoint of CV death or hospitalization due to heart failure.**

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End point title	Time to first event included in the composite endpoint of CV death or hospitalization due to heart failure.
End point description:	
Co-primary efficacy	
End point type	Primary
End point timeframe:	
up to 5.2 years	

<b>End point values</b>	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8582	8578		
Units: Participants				
Number of patients with an event	417	496		

**Statistical analyses**

<b>Statistical analysis title</b>	Cox regression
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	17160
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.95

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**Secondary: Time to first event of renal composite endpoint: Confirmed sustained  $\geq 40\%$  decrease in eGFR to eGFR  $< 60$  ml/min/1.73m<sup>2</sup> and/or ESRD and/or renal or CV death.**

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End point title	Time to first event of renal composite endpoint: Confirmed sustained $\geq 40\%$ decrease in eGFR to eGFR $< 60$ ml/min/1.73m <sup>2</sup> and/or ESRD and/or renal or CV death.
End point description:	
Secondary	

End point type	Secondary
End point timeframe:	
up to 5.2 years	

<b>End point values</b>	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8582	8578		
Units: Participants				
Number of patients with an event	370	480		

### Statistical analyses

<b>Statistical analysis title</b>	Cox regression
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	17160
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.87

### Secondary: Time to All-cause mortality.

End point title	Time to All-cause mortality.
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
up to 5.2 years	

<b>End point values</b>	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8582	8578		
Units: Participants				
Number of patients with an event	529	570		

### Statistical analyses

<b>Statistical analysis title</b>	Cox regression
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	17160
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.198
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.04

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

up to 5.2 years

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	21
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Matching placebo for dapagliflozin 10 mg administered orally once daily

Reporting group title	Dapa 10 mg
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Reporting group description:

Dapagliflozin 10 mg tablets administered orally once daily

<b>Serious adverse events</b>	Placebo	Dapa 10 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	3418 / 8569 (39.89%)	3205 / 8574 (37.38%)	
number of deaths (all causes)	569	529	
number of deaths resulting from adverse events	566	527	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acral lentiginous melanoma			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Acute myelomonocytic leukaemia			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			

subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma gastric		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Adenocarcinoma of appendix		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	18 / 8569 (0.21%)	20 / 8574 (0.23%)
occurrences causally related to treatment / all	0 / 18	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 1
Adenocarcinoma pancreas		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 5	1 / 1
Adenoid cystic carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenoma benign		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal neoplasm		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenocortical carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal squamous cell carcinoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anaplastic astrocytoma		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Anaplastic large-cell lymphoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	27 / 8569 (0.32%)	34 / 8574 (0.40%)
occurrences causally related to treatment / all	0 / 37	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Benign breast neoplasm		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign ear neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastrointestinal neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign hepatic neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign laryngeal neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lymph node neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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 bladder		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of adrenal gland		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of spinal cord		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign ovarian tumour		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign pancreatic neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign renal neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign soft tissue neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	25 / 8569 (0.29%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	3 / 25	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage 0, with cancer in situ		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder papilloma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (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		
subjects affected / exposed	8 / 8569 (0.09%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	2 / 8	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Bladder transitional cell carcinoma metastatic		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
<b>Bone cancer</b>		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone cancer metastatic</b>		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Bone neoplasm</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bowen's disease</b>		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain neoplasm</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Brain neoplasm benign</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain neoplasm malignant</b>		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Breast cancer</b>		

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer female</b>		
subjects affected / exposed	20 / 8569 (0.23%)	19 / 8574 (0.22%)
occurrences causally related to treatment / all	0 / 22	2 / 20
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Breast cancer metastatic</b>		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast neoplasm</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchial carcinoma</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cancer pain</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carcinoid tumour of the duodenum</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carcinoid tumour of the small bowel</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Central nervous system lymphoma</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cervix carcinoma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	7 / 8569 (0.08%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	1 / 7	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 5
Chondromatosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chondrosarcoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic leukaemia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	6 / 8569 (0.07%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		

subjects affected / exposed	0 / 8569 (0.00%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Colon adenoma		
subjects affected / exposed	7 / 8569 (0.08%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	16 / 8569 (0.19%)	16 / 8574 (0.19%)
occurrences causally related to treatment / all	0 / 16	0 / 17
deaths causally related to treatment / all	0 / 2	0 / 2
Colon cancer metastatic		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Colon neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Colorectal cancer metastatic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Dermatofibrosarcoma protuberans		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	7 / 8569 (0.08%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Endometrial cancer		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer metastatic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fallopian tube cancer metastatic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Follicular thyroid cancer		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroadenoma of breast		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cancer metastatic		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gallbladder adenocarcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric adenoma		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	8 / 8569 (0.09%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Gastric cancer stage 0		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal adenocarcinoma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal cancer		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival cancer		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Glioblastoma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma multiforme		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Glottis carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangioma		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangiopericytoma		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hairy cell leukaemia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		
subjects affected / exposed	5 / 8569 (0.06%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 5	0 / 1
Hepatic cancer metastatic		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	4 / 8569 (0.05%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 4
Hodgkin's disease		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hypopharyngeal cancer		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Infected neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal adenocarcinoma		

subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	2 / 8569 (0.02%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	5 / 8569 (0.06%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive lobular breast carcinoma		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Juvenile melanoma benign		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Keratoacanthoma		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine benign neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		

subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Laryngeal cancer metastatic		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Laryngeal squamous cell carcinoma		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo maligna		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukaemia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Lipoma		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liposarcoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	6 / 8569 (0.07%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	1 / 7	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Lung cancer metastatic		

subjects affected / exposed	14 / 8569 (0.16%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 14	0 / 12
deaths causally related to treatment / all	0 / 13	0 / 6
Lung carcinoma cell type unspecified stage 0		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2
Lung neoplasm malignant		
subjects affected / exposed	21 / 8569 (0.25%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 21	0 / 13
deaths causally related to treatment / all	0 / 4	0 / 6
Lung squamous cell carcinoma metastatic		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Lymphocytic leukaemia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	1 / 8569 (0.01%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	1 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant anorectal neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		

subjects affected / exposed	12 / 8569 (0.14%)	13 / 8574 (0.15%)
occurrences causally related to treatment / all	0 / 12	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma in situ		
subjects affected / exposed	4 / 8569 (0.05%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of pleura metastatic		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant neoplasm of renal pelvis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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 unknown primary site		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant peritoneal neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melanocytic naevus		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melanoma recurrent		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningioma</b>		
subjects affected / exposed	1 / 8569 (0.01%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningioma benign</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesothelioma malignant</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Metastases to adrenals</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to bone</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to central nervous system</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to lymph nodes</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to lung</b>		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to peritoneum			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to rectum			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spinal cord			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic bronchial carcinoma			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic carcinoma of the bladder			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic gastric cancer			
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Metastatic neoplasm			

subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	5 / 8569 (0.06%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 2
Metastatic renal cell carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic squamous cell carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Monoclonal gammopathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	0 / 8569 (0.00%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Myeloproliferative neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Nasopharyngeal cancer		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
<b>Neoplasm</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neoplasm prostate</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neuroendocrine tumour</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neoplasm skin</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neuroendocrine tumour of the lung</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Non-small cell lung cancer</b>			
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neuroendocrine tumour of the lung metastatic</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Non-small cell lung cancer metastatic</b>			

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ocular neoplasm			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer recurrent			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal adenocarcinoma			
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Oesophageal carcinoma			
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral neoplasm benign			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal cancer			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoma			

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer metastatic		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic carcinoma		
subjects affected / exposed	8 / 8569 (0.09%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 5	0 / 5
Pancreatic carcinoma metastatic		
subjects affected / exposed	9 / 8569 (0.11%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 6	0 / 7
Pancreatic neoplasm		

subjects affected / exposed	0 / 8569 (0.00%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Pancreatic neuroendocrine tumour		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatoblastoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary cystadenoma lymphomatosum		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary renal cell carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary serous endometrial carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary tumour of renal pelvis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Parathyroid tumour benign		

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Penile squamous cell carcinoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal carcinoma metastatic		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pheochromocytoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cancer		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell leukaemia		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Plasma cell myeloma		
subjects affected / exposed	6 / 8569 (0.07%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Pleomorphic adenoma		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	55 / 8569 (0.64%)	69 / 8574 (0.80%)
occurrences causally related to treatment / all	0 / 55	3 / 70
deaths causally related to treatment / all	0 / 2	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	7 / 8569 (0.08%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer recurrent		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenoma		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	4 / 8569 (0.05%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal cancer metastatic		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cancer		
subjects affected / exposed	7 / 8569 (0.08%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 8	1 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cell carcinoma		
subjects affected / exposed	8 / 8569 (0.09%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 8	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	4 / 8569 (0.05%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 4	1 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Retro-orbital neoplasm		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Salivary gland neoplasm		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sebacaceous carcinoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seborrhoeic keratosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Signet-ring cell carcinoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	3 / 8569 (0.04%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 2
Small cell lung cancer extensive stage		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small cell lung cancer metastatic		
subjects affected / exposed	4 / 8569 (0.05%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0
Soft tissue sarcoma		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine adenocarcinoma		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Spinal cord neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	10 / 8569 (0.12%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
Squamous cell carcinoma of skin		
subjects affected / exposed	9 / 8569 (0.11%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
T-cell lymphoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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 tongue		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Throat cancer		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid adenoma		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer metastatic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid neoplasm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	12 / 8569 (0.14%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	5 / 14	3 / 11
deaths causally related to treatment / all	0 / 1	0 / 0
Tonsil cancer		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell cancer of the renal pelvis and ureter		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma recurrent		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour obstruction		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma metastatic		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Uterine cancer		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal cancer stage 0		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval cancer		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Vocal cord neoplasm		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval cancer stage 0		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage II		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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 I		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Endometrial cancer stage I		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer stage III		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage III		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage IV		

subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
<b>Malignant neoplasm of ampulla of Vater</b>			
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Non-Hodgkin's lymphoma</b>			
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Non-Hodgkin's lymphoma stage IV</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Non-small cell lung cancer stage IV</b>			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
<b>Prostate cancer stage IV</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular disorders</b>			
<b>Accelerated hypertension</b>			
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic aneurysm</b>			
subjects affected / exposed	10 / 8569 (0.12%)	12 / 8574 (0.14%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 2	0 / 0	
<b>Aortic aneurysm rupture</b>			

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angiopathy		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic stenosis		
subjects affected / exposed	17 / 8569 (0.20%)	22 / 8574 (0.26%)
occurrences causally related to treatment / all	0 / 17	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dilatation		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial occlusive disease		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial insufficiency		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial disorder		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial thrombosis		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial perforation		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1
Arteritis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bleeding varicose vein		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure fluctuation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Claudication of jaw muscles		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	12 / 8569 (0.14%)	17 / 8574 (0.20%)
occurrences causally related to treatment / all	0 / 12	2 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Essential hypertension		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	4 / 8569 (0.05%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery aneurysm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma</b>		
subjects affected / exposed	6 / 8569 (0.07%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhagic vasculitis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertension</b>		
subjects affected / exposed	27 / 8569 (0.32%)	27 / 8574 (0.31%)
occurrences causally related to treatment / all	0 / 31	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Hypertensive crisis</b>		
subjects affected / exposed	24 / 8569 (0.28%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	0 / 28	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive emergency</b>		
subjects affected / exposed	7 / 8569 (0.08%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypotension</b>		
subjects affected / exposed	14 / 8569 (0.16%)	28 / 8574 (0.33%)
occurrences causally related to treatment / all	1 / 14	2 / 29
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hypovolaemic shock</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Iliac artery disease</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery embolism		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	3 / 8569 (0.04%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Internal haemorrhage		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemia		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Ischaemic limb pain		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jugular vein thrombosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphatic fistula		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microangiopathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.14%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 13	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	49 / 8569 (0.57%)	43 / 8574 (0.50%)
occurrences causally related to treatment / all	0 / 53	0 / 56
deaths causally related to treatment / all	0 / 1	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery dissection		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery haematoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	15 / 8569 (0.18%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	0 / 20	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	20 / 8569 (0.23%)	23 / 8574 (0.27%)
occurrences causally related to treatment / all	0 / 22	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	4 / 8569 (0.05%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	19 / 8569 (0.22%)	34 / 8574 (0.40%)
occurrences causally related to treatment / all	0 / 21	1 / 46
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	35 / 8569 (0.41%)	30 / 8574 (0.35%)
occurrences causally related to treatment / all	0 / 41	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		

subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Raynaud's phenomenon		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Shock haemorrhagic		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Subclavian artery occlusion		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian steal syndrome		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Superior vena cava stenosis		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Temporal arteritis		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thromboangiitis obliterans		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular occlusion		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasospasm			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	10 / 8569 (0.12%)	4 / 8574 (0.05%)	
occurrences causally related to treatment / all	0 / 10	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Chest pain		
subjects affected / exposed	20 / 8569 (0.23%)	29 / 8574 (0.34%)
occurrences causally related to treatment / all	0 / 20	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac death		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Complication associated with device		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Critical illness		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	89 / 8569 (1.04%)	81 / 8574 (0.94%)
occurrences causally related to treatment / all	0 / 89	0 / 81
deaths causally related to treatment / all	0 / 89	0 / 81
Dehiscence		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Drug intolerance		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise tolerance decreased		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Drug withdrawal syndrome</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gait disturbance</b>		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>General physical health deterioration</b>		
subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Generalised oedema</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hernia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Granuloma</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypothermia</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Impaired healing</b>		

subjects affected / exposed	3 / 8569 (0.04%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Implant site inflammation</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incarcerated hernia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inflammation</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical device pain</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malaise</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical device site irritation</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Microlithiasis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple organ dysfunction syndrome</b>		

subjects affected / exposed	8 / 8569 (0.09%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	1 / 8	0 / 9
deaths causally related to treatment / all	0 / 5	0 / 4
<b>Necrobiosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Necrosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-cardiac chest pain</b>		
subjects affected / exposed	107 / 8569 (1.25%)	93 / 8574 (1.08%)
occurrences causally related to treatment / all	1 / 120	0 / 110
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema peripheral</b>		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Organ failure</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pacemaker syndrome</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic mass		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	13 / 8569 (0.15%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 13	1 / 14
deaths causally related to treatment / all	0 / 1	0 / 0
Soft tissue inflammation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-graft endoleak		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Submandibular mass		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	16 / 8569 (0.19%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	0 / 16	0 / 14
deaths causally related to treatment / all	0 / 16	0 / 14
Sudden death		

subjects affected / exposed	23 / 8569 (0.27%)	21 / 8574 (0.24%)	
occurrences causally related to treatment / all	0 / 23	0 / 21	
deaths causally related to treatment / all	0 / 23	0 / 21	
Systemic inflammatory response syndrome			
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	8 / 8569 (0.09%)	7 / 8574 (0.08%)	
occurrences causally related to treatment / all	1 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to metals			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to vaccine			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			

subjects affected / exposed	5 / 8569 (0.06%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Drug hypersensitivity</b>			
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hashitoxicosis</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypersensitivity</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sarcoidosis</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
<b>Acquired hydrocele</b>			
subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acquired phimosis</b>			
subjects affected / exposed	1 / 8569 (0.01%)	11 / 8574 (0.13%)	
occurrences causally related to treatment / all	0 / 1	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Balanoposthitis</b>			
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Benign prostatic hyperplasia</b>			

subjects affected / exposed	31 / 8569 (0.36%)	28 / 8574 (0.33%)
occurrences causally related to treatment / all	0 / 31	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast mass</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast pain</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervical dysplasia</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colpocele</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cystocele</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Endometrial hyperplasia</b>		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Endometrial hypertrophy</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erectile dysfunction</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gynaecomastia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrosalpinx		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic haemorrhage		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic prolapse		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Penile necrosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peyronie's disease		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic disorder		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	8 / 8569 (0.09%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	2 / 9	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatomegaly		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular cyst		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine polyp		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine prolapse		

subjects affected / exposed	2 / 8569 (0.02%)	6 / 8574 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uterovaginal prolapse</b>			
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vaginal dysplasia</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vaginal prolapse</b>			
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Varicocele</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>Acute pulmonary oedema</b>			
subjects affected / exposed	8 / 8569 (0.09%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	1 / 8	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Acute respiratory distress syndrome</b>			
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
<b>Acute respiratory failure</b>			
subjects affected / exposed	43 / 8569 (0.50%)	37 / 8574 (0.43%)	
occurrences causally related to treatment / all	0 / 50	0 / 41	
deaths causally related to treatment / all	0 / 12	0 / 5	
<b>Alveolitis allergic</b>			

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Apnoea		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aspiration		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma		
subjects affected / exposed	18 / 8569 (0.21%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 21	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma-chronic obstructive pulmonary disease overlap syndrome		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asthmatic crisis		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial hyperreactivity		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		

subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	54 / 8569 (0.63%)	54 / 8574 (0.63%)
occurrences causally related to treatment / all	0 / 90	1 / 81
deaths causally related to treatment / all	0 / 5	0 / 5
Chronic respiratory failure		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Dyspnoea		
subjects affected / exposed	21 / 8569 (0.25%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 22	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Dyspnoea exertional		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemoptysis</b>		
subjects affected / exposed	2 / 8569 (0.02%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemothorax</b>		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydrothorax</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Interstitial lung disease</b>		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Hypoxia</b>		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Idiopathic pulmonary fibrosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lung disorder</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lung infiltration</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal polyps		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Paraneoplastic pleural effusion		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Obstructive airways disorder		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pickwickian syndrome		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	13 / 8569 (0.15%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 14	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Pleural thickening		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		

subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	10 / 8569 (0.12%)	18 / 8574 (0.21%)
occurrences causally related to treatment / all	0 / 10	0 / 19
deaths causally related to treatment / all	0 / 2	0 / 2
Pulmonary amyloidosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis		
subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	4 / 8569 (0.05%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary arterial hypertension		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	0 / 8569 (0.00%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		

subjects affected / exposed	27 / 8569 (0.32%)	26 / 8574 (0.30%)
occurrences causally related to treatment / all	0 / 27	1 / 26
deaths causally related to treatment / all	0 / 8	0 / 5
Pulmonary hypertension		
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 19	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary haemorrhage		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary fibrosis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary infarction		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary mass		
subjects affected / exposed	11 / 8569 (0.13%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux laryngitis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	15 / 8569 (0.18%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	2 / 16	0 / 4
deaths causally related to treatment / all	1 / 4	0 / 0
Pulmonary thrombosis		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory acidosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory distress		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		
subjects affected / exposed	24 / 8569 (0.28%)	29 / 8574 (0.34%)
occurrences causally related to treatment / all	0 / 28	1 / 30
deaths causally related to treatment / all	0 / 9	0 / 7
Restrictive pulmonary disease		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid lung		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinitis hypertrophic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		

subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord leukoplakia			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment disorder			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			

subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Confusional state		
subjects affected / exposed	12 / 8569 (0.14%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	2 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Conversion disorder		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed mood		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	13 / 8569 (0.15%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 15	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Drug abuse		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomania		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Major depression</b>		
subjects affected / exposed	6 / 8569 (0.07%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental status changes</b>		
subjects affected / exposed	7 / 8569 (0.08%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Mood disorder due to a general medical condition</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Panic attack</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post-traumatic stress disorder</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Restlessness</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Schizoaffective disorder</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Schizophrenia</b>		

subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective disorder depressive type			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep disorder			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device breakage			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device lead damage</b>			
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device malfunction</b>			
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device occlusion</b>			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Stent malfunction</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatobiliary disorders</b>			
<b>Bile duct obstruction</b>			
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bile duct stenosis</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bile duct stone</b>			
subjects affected / exposed	8 / 8569 (0.09%)	9 / 8574 (0.10%)	
occurrences causally related to treatment / all	0 / 8	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Biliary colic</b>			

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary dyskinesia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary dyspepsia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	5 / 8569 (0.06%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Cholecystitis		
subjects affected / exposed	22 / 8569 (0.26%)	18 / 8574 (0.21%)
occurrences causally related to treatment / all	0 / 23	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	22 / 8569 (0.26%)	25 / 8574 (0.29%)
occurrences causally related to treatment / all	0 / 22	0 / 25
deaths causally related to treatment / all	0 / 1	0 / 0
Cholecystitis chronic		
subjects affected / exposed	6 / 8569 (0.07%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		

subjects affected / exposed	38 / 8569 (0.44%)	26 / 8574 (0.30%)
occurrences causally related to treatment / all	1 / 40	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatic failure		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cholesterolosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder perforation		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder polyp		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	11 / 8569 (0.13%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	2 / 13	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 1
Hepatic cyst		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		

subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic fibrosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic mass		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatorenal syndrome		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocholecystis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Jaundice</b>			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Liver injury</b>			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Non-alcoholic steatohepatitis</b>			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Porcelain gallbladder</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Portal vein thrombosis</b>			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Investigations</b>			
<b>Anticoagulation drug level below therapeutic</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood creatine phosphokinase increased</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood creatinine increased</b>			

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Blood glucose abnormal</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Blood glucose increased</b>		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Blood pressure increased</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Blood pressure decreased</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Catheterisation cardiac</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain natriuretic peptide increased</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>General physical condition abnormal</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Glomerular filtration rate decreased</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test increased		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transaminases increased		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	7 / 8569 (0.08%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Urine cytology abnormal		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QT prolonged		

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment elevation			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C antibody positive			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin T increased			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall wound			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wound dehiscence			
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			

subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Accidental poisoning		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acetabulum fracture		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol poisoning		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Allergic transfusion reaction		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia postoperative		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Anastomotic leak		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anastomotic ulcer		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		

subjects affected / exposed	14 / 8569 (0.16%)	19 / 8574 (0.22%)
occurrences causally related to treatment / all	0 / 14	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial bypass occlusion		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial injury		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Back injury		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Avulsion fracture		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone contusion		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac procedure complication		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac valve replacement complication		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage injury		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract operation complication		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cement embolism		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest crushing		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Chest injury		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complications of transplanted liver		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Compression fracture		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	7 / 8569 (0.08%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	4 / 8569 (0.05%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Confusion postoperative		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		

subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary bypass stenosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Costal cartilage fracture		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	3 / 8569 (0.04%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3
Cystitis radiation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exposure to toxic agent		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid injury		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		

subjects affected / exposed	4 / 8569 (0.05%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	9 / 8569 (0.11%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	20 / 8569 (0.23%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	1 / 20	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	18 / 8569 (0.21%)	16 / 8574 (0.19%)
occurrences causally related to treatment / all	1 / 18	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	4 / 8569 (0.05%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in gastrointestinal tract		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in respiratory tract		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture displacement		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured sacrum		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gun shot wound		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haematuria traumatic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Heat stroke		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	8 / 8569 (0.09%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
Hip fracture		
subjects affected / exposed	15 / 8569 (0.18%)	13 / 8574 (0.15%)
occurrences causally related to treatment / all	0 / 16	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Ilium fracture		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Humerus fracture</b>		
subjects affected / exposed	20 / 8569 (0.23%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	2 / 20	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Injury</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Incisional hernia</b>		
subjects affected / exposed	2 / 8569 (0.02%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intentional overdose</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Jaw fracture</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint dislocation</b>		
subjects affected / exposed	1 / 8569 (0.01%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint injury</b>		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laceration</b>		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb fracture		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	4 / 8569 (0.05%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 4	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lisfranc fracture		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	9 / 8569 (0.11%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar vertebral fracture</b>		
subjects affected / exposed	6 / 8569 (0.07%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meniscus injury</b>		
subjects affected / exposed	2 / 8569 (0.02%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple fractures</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple injuries</b>		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle strain</b>		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle rupture</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nerve injury</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ocular procedural complication</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Overdose</b>		
subjects affected / exposed	6 / 8569 (0.07%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	1 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Patella fracture</b>		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic fracture</b>		
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periorbital haematoma</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periprocedural myocardial infarction</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peripheral artery restenosis</b>		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periprosthetic fracture</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax traumatic</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumoconiosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post concussion syndrome</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural complication</b>		
subjects affected / exposed	14 / 8569 (0.16%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 14	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Post laminectomy syndrome</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural constipation</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural discharge</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural haematoma</b>		
subjects affected / exposed	1 / 8569 (0.01%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural haematuria</b>		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	4 / 8569 (0.05%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1
Post procedural inflammation		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural myocardial infarction		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative delirium		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thoracic procedure complication		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thrombosis		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural shock		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pubis fracture		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation oesophagitis		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal laceration postoperative		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	10 / 8569 (0.12%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 10	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	15 / 8569 (0.18%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 17	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	7 / 8569 (0.08%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 2
Sedation complication		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin abrasion		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin injury		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin wound		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	6 / 8569 (0.07%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue injury		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	4 / 8569 (0.05%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	4 / 8569 (0.05%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic injury		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic rupture		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stab wound		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Sternal fracture		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma site haemorrhage		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	9 / 8569 (0.11%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 9	1 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
Subcutaneous haematoma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	11 / 8569 (0.13%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Subdural haemorrhage		

subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Tendon injury		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	8 / 8569 (0.09%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	6 / 8569 (0.07%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	5 / 8569 (0.06%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue injury		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transfusion reaction		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transplant dysfunction		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic arthritis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic fracture		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (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	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	4 / 8569 (0.05%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft restenosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	5 / 8569 (0.06%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Wound haematoma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		

subjects affected / exposed	5 / 8569 (0.06%)	6 / 8574 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Congenital, familial and genetic disorders</b>			
Adenomatous polyposis coli			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital hepatobiliary anomaly			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart disease congenital			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitello-intestinal duct remnant			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis Meckel's			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			

Acute cardiac event		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Acute coronary syndrome		
subjects affected / exposed	31 / 8569 (0.36%)	17 / 8574 (0.20%)
occurrences causally related to treatment / all	0 / 33	0 / 22
deaths causally related to treatment / all	0 / 4	0 / 1
Acute left ventricular failure		
subjects affected / exposed	17 / 8569 (0.20%)	16 / 8574 (0.19%)
occurrences causally related to treatment / all	0 / 23	0 / 22
deaths causally related to treatment / all	0 / 1	0 / 1
Acute myocardial infarction		
subjects affected / exposed	233 / 8569 (2.72%)	265 / 8574 (3.09%)
occurrences causally related to treatment / all	7 / 264	3 / 293
deaths causally related to treatment / all	0 / 18	0 / 24
Angina pectoris		
subjects affected / exposed	159 / 8569 (1.86%)	154 / 8574 (1.80%)
occurrences causally related to treatment / all	1 / 175	0 / 178
deaths causally related to treatment / all	0 / 1	0 / 0
Angina unstable		
subjects affected / exposed	269 / 8569 (3.14%)	271 / 8574 (3.16%)
occurrences causally related to treatment / all	4 / 332	2 / 349
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve calcification		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease mixed		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	2 / 8569 (0.02%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	6 / 8569 (0.07%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 1
Arteriosclerosis coronary artery		
subjects affected / exposed	16 / 8569 (0.19%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	1 / 21	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Atrial fibrillation		
subjects affected / exposed	139 / 8569 (1.62%)	117 / 8574 (1.36%)
occurrences causally related to treatment / all	3 / 177	1 / 138
deaths causally related to treatment / all	0 / 1	0 / 2
Atrial flutter		
subjects affected / exposed	34 / 8569 (0.40%)	21 / 8574 (0.24%)
occurrences causally related to treatment / all	0 / 44	1 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		

subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block</b>		
subjects affected / exposed	7 / 8569 (0.08%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 7	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block complete</b>		
subjects affected / exposed	14 / 8569 (0.16%)	19 / 8574 (0.22%)
occurrences causally related to treatment / all	0 / 14	0 / 19
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Atrioventricular block second degree</b>		
subjects affected / exposed	7 / 8569 (0.08%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradyarrhythmia</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradycardia</b>		
subjects affected / exposed	21 / 8569 (0.25%)	16 / 8574 (0.19%)
occurrences causally related to treatment / all	0 / 22	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Bifascicular block</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bundle branch block left</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bundle branch block right</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	31 / 8569 (0.36%)	33 / 8574 (0.38%)
occurrences causally related to treatment / all	1 / 32	1 / 34
deaths causally related to treatment / all	0 / 19	1 / 28
Cardiac asthma		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac disorder		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	188 / 8569 (2.19%)	147 / 8574 (1.71%)
occurrences causally related to treatment / all	4 / 252	2 / 199
deaths causally related to treatment / all	0 / 12	0 / 24
Cardiac failure acute		
subjects affected / exposed	31 / 8569 (0.36%)	22 / 8574 (0.26%)
occurrences causally related to treatment / all	0 / 39	0 / 25
deaths causally related to treatment / all	0 / 7	0 / 6
Cardiac failure congestive		
subjects affected / exposed	147 / 8569 (1.72%)	121 / 8574 (1.41%)
occurrences causally related to treatment / all	4 / 205	0 / 177
deaths causally related to treatment / all	0 / 9	0 / 12
Cardiac failure chronic		
subjects affected / exposed	20 / 8569 (0.23%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 23	1 / 14
deaths causally related to treatment / all	0 / 2	0 / 0
Cardiac ventricular thrombosis		

subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	11 / 8569 (0.13%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	1 / 11	0 / 12
deaths causally related to treatment / all	0 / 8	0 / 12
Cardiogenic shock		
subjects affected / exposed	13 / 8569 (0.15%)	19 / 8574 (0.22%)
occurrences causally related to treatment / all	0 / 16	0 / 19
deaths causally related to treatment / all	0 / 6	0 / 14
Cardiomegaly		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		
subjects affected / exposed	8 / 8569 (0.09%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiomyopathy acute		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	7 / 8569 (0.08%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 6	0 / 2
Cardiovascular insufficiency		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Cardiovascular disorder</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronotropic incompetence</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic left ventricular failure</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Congestive cardiomyopathy</b>		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Conduction disorder</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cor pulmonale</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary artery aneurysm</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary artery occlusion</b>		

subjects affected / exposed	5 / 8569 (0.06%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	84 / 8569 (0.98%)	106 / 8574 (1.24%)
occurrences causally related to treatment / all	1 / 87	5 / 113
deaths causally related to treatment / all	1 / 3	0 / 5
Coronary artery stenosis		
subjects affected / exposed	22 / 8569 (0.26%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 23	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Coronary ostial stenosis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dressler's syndrome		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic dysfunction		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart valve stenosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	18 / 8569 (0.21%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 18	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Left ventricular failure		
subjects affected / exposed	13 / 8569 (0.15%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 13	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	6 / 8569 (0.07%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve stenosis		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		

subjects affected / exposed	108 / 8569 (1.26%)	96 / 8574 (1.12%)
occurrences causally related to treatment / all	2 / 111	1 / 104
deaths causally related to treatment / all	0 / 24	0 / 19
<b>Myocarditis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial ischaemia</b>		
subjects affected / exposed	54 / 8569 (0.63%)	47 / 8574 (0.55%)
occurrences causally related to treatment / all	0 / 61	0 / 49
deaths causally related to treatment / all	0 / 3	0 / 4
<b>Nodal arrhythmia</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Palpitations</b>		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial effusion</b>		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericarditis</b>		
subjects affected / exposed	4 / 8569 (0.05%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Postinfarction angina</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Prinzmetal angina</b>		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulseless electrical activity</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rheumatic heart disease</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Right ventricular failure</b>		
subjects affected / exposed	4 / 8569 (0.05%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Sinus arrest</b>		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus bradycardia</b>		
subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus node dysfunction</b>		
subjects affected / exposed	13 / 8569 (0.15%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	0 / 14	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus tachycardia</b>		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Supraventricular tachycardia</b>		

subjects affected / exposed	6 / 8569 (0.07%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	5 / 8569 (0.06%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Torsade de pointes		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Ventricular extrasystoles		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular failure		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular fibrillation</b>			
subjects affected / exposed	9 / 8569 (0.11%)	8 / 8574 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 4	
<b>Ventricular tachycardia</b>			
subjects affected / exposed	15 / 8569 (0.18%)	19 / 8574 (0.22%)	
occurrences causally related to treatment / all	1 / 21	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Adams-Stokes syndrome</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nervous system disorders</b>			
<b>Amnesia</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Amyotrophic lateral sclerosis</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Aphasia</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arachnoid cyst</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ataxia</b>			

subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Autonomic failure syndrome		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Balance disorder		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basal ganglia infarction		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basilar artery perforation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Brain injury		
subjects affected / exposed	6 / 8569 (0.07%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
Brain oedema		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Brain stem infarction		
subjects affected / exposed	3 / 8569 (0.04%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Brain stem haemorrhage		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain stem stroke</b>		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid arteriosclerosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Burning sensation</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery occlusion</b>		
subjects affected / exposed	1 / 8569 (0.01%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery stenosis</b>		
subjects affected / exposed	21 / 8569 (0.25%)	27 / 8574 (0.31%)
occurrences causally related to treatment / all	0 / 22	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery insufficiency</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid sinus syndrome</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carpal tunnel syndrome</b>		

subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar ataxia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	2 / 8569 (0.02%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebellar stroke		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery embolism		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery occlusion		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral atrophy		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	6 / 8569 (0.07%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 2
Cerebral infarction		
subjects affected / exposed	32 / 8569 (0.37%)	24 / 8574 (0.28%)
occurrences causally related to treatment / all	2 / 33	1 / 27
deaths causally related to treatment / all	0 / 3	0 / 4
Cerebral ischaemia		
subjects affected / exposed	9 / 8569 (0.11%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	88 / 8569 (1.03%)	102 / 8574 (1.19%)
occurrences causally related to treatment / all	3 / 94	2 / 112
deaths causally related to treatment / all	0 / 11	0 / 10
Cerebrovascular disorder		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical cord compression		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		

subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cluster headache		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cranial nerve palsies multiple		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelinating polyneuropathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic autonomic neuropathy		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic hyperosmolar coma		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic coma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	4 / 8569 (0.05%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	9 / 8569 (0.11%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	1 / 9	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dystonic tremor		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		

subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	8 / 8569 (0.09%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	5 / 8569 (0.06%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Essential tremor		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	8 / 8569 (0.09%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Focal dyscognitive seizures		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		

subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic cerebral infarction		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	11 / 8569 (0.13%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 3
Haemorrhagic transformation stroke		
subjects affected / exposed	4 / 8569 (0.05%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Headache		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hemianopia homonymous		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		

subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Hypoaesthesia		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic encephalopathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokinesia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intensive care unit acquired weakness		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intraventricular haemorrhage		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Ischaemic cerebral infarction		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	90 / 8569 (1.05%)	97 / 8574 (1.13%)
occurrences causally related to treatment / all	0 / 99	2 / 105
deaths causally related to treatment / all	0 / 7	0 / 6
Lacunar infarction		
subjects affected / exposed	14 / 8569 (0.16%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	0 / 14	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Lateral medullary syndrome		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar radiculopathy</b>		
subjects affected / exposed	6 / 8569 (0.07%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Loss of consciousness</b>		
subjects affected / exposed	6 / 8569 (0.07%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Lumbosacral radiculopathy</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medication overuse headache</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Memory impairment</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic encephalopathy</b>		
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Migraine</b>		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple system atrophy</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myasthenia gravis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle contractions involuntary</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelopathy</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nerve compression</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nervous system disorder</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuralgia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurological symptom</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurodegenerative disorder</b>		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Occipital neuralgia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peroneal nerve palsy		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (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	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post herpetic neuralgia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Postictal paralysis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Quadriplegia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular syndrome		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (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	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ruptured cerebral aneurysm</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Sciatica</b>		
subjects affected / exposed	7 / 8569 (0.08%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Seizure</b>		
subjects affected / exposed	10 / 8569 (0.12%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	1 / 10	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Simple partial seizures</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Somnolence</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal claudication</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylitic myelopathy</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stiff person syndrome</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Status epilepticus</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subdural hygroma</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stroke in evolution</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Syncope</b>		
subjects affected / exposed	41 / 8569 (0.48%)	37 / 8574 (0.43%)
occurrences causally related to treatment / all	2 / 44	3 / 38
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thalamic infarction</b>		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thoracic outlet syndrome</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tension headache</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Toxic encephalopathy</b>		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic stroke		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Thrombotic cerebral infarction		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic neuropathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	54 / 8569 (0.63%)	68 / 8574 (0.79%)
occurrences causally related to treatment / all	1 / 59	1 / 76
deaths causally related to treatment / all	0 / 1	0 / 0
Vascular encephalopathy		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord paralysis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia with Lewy bodies		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
VIth nerve paralysis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
VIth nerve paresis		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wernicke-Korsakoff syndrome			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	28 / 8569 (0.33%)	20 / 8574 (0.23%)	
occurrences causally related to treatment / all	0 / 30	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of chronic disease			
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Elephantiasis			

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hilar lymphadenopathy		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile neutropenia		
subjects affected / exposed	4 / 8569 (0.05%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	18 / 8569 (0.21%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 18	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		

subjects affected / exposed	1 / 8569 (0.01%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neutropenia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Normocytic anaemia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Microcytic anaemia</b>		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Plasmacytosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancytopenia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splenic cyst</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splenic infarction</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thrombocytopenic purpura</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	3 / 8569 (0.04%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (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	1 / 8569 (0.01%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	12 / 8569 (0.14%)	11 / 8574 (0.13%)	
occurrences causally related to treatment / all	0 / 13	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo labyrinthine			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	8 / 8569 (0.09%)	5 / 8574 (0.06%)	
occurrences causally related to treatment / all	1 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular ataxia			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amblyopia			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness transient			

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Astigmatism		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract		
subjects affected / exposed	26 / 8569 (0.30%)	28 / 8574 (0.33%)
occurrences causally related to treatment / all	0 / 32	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract nuclear		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract subcapsular		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal deposits		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	1 / 8569 (0.01%)	0 / 8574 (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	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		

subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocrine ophthalmopathy		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exophthalmos		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemorrhage		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Iridocyclitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iritis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lagophthalmos		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Macular fibrosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Macular degeneration</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Macular oedema</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Maculopathy</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal artery occlusion</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal detachment</b>		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal haemorrhage</b>		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal tear</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal vascular occlusion</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tractional retinal detachment</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal vein occlusion</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ulcerative keratitis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vision blurred</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Visual impairment</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vitreous haemorrhage</b>		
subjects affected / exposed	6 / 8569 (0.07%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tolosa-Hunt syndrome</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal disorders</b>			
<b>Abdominal discomfort</b>			
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal adhesions</b>			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal incarcerated hernia</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal hernia</b>			
subjects affected / exposed	7 / 8569 (0.08%)	4 / 8574 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal hernia obstructive</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal pain lower</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal pain</b>			
subjects affected / exposed	9 / 8569 (0.11%)	13 / 8574 (0.15%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal pain upper</b>			

subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acute haemorrhagic ulcerative colitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholic pancreatitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (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	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	11 / 8569 (0.13%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis microscopic		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	2 / 8569 (0.02%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	3 / 8569 (0.04%)	13 / 8574 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroenteropathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dieulafoy's vascular malformation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	11 / 8569 (0.13%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	1 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		

subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	2 / 8569 (0.02%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	2 / 8569 (0.02%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		

subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocutaneous fistula		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epigastric discomfort		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epiploic appendagitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 8569 (0.00%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Faeces discoloured		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		

subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric perforation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric stenosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	11 / 8569 (0.13%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	20 / 8569 (0.23%)	13 / 8574 (0.15%)
occurrences causally related to treatment / all	1 / 20	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		

subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	18 / 8569 (0.21%)	17 / 8574 (0.20%)
occurrences causally related to treatment / all	0 / 18	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal inflammation		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal obstruction		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal perforation		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	10 / 8569 (0.12%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival bleeding		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hernial eventration		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated umbilical hernia		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	13 / 8569 (0.15%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal fibrosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal infarction		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Intestinal ischaemia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal perforation</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal obstruction</b>		
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal polyp</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal pseudo-obstruction</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intra-abdominal fluid collection</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Jejunal perforation</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intra-abdominal haemorrhage</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intussusception		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer haemorrhage		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	9 / 8569 (0.11%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Lumbar hernia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery embolism		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mesenteric artery stenosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric panniculitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric vascular insufficiency		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Obstruction gastric		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Odynophagia		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal food impaction		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal obstruction		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal perforation		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis ulcerative		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Palatal oedema		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic duct obstruction		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic pseudocyst		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic necrosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	12 / 8569 (0.14%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	1 / 12	1 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatitis acute		
subjects affected / exposed	15 / 8569 (0.18%)	13 / 8574 (0.15%)
occurrences causally related to treatment / all	1 / 17	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis relapsing		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		

subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis necrotising		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatolithiasis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontal disease		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal adhesions		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumoperitoneum		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Portal hypertensive gastropathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	2 / 8569 (0.02%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cyst		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	9 / 8569 (0.11%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal haemorrhage		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine ulcer		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Steatorrhoea		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis mesenteric vessel		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Umbilical hernia		
subjects affected / exposed	9 / 8569 (0.11%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		
subjects affected / exposed	9 / 8569 (0.11%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Upper gastrointestinal haemorrhage		
subjects affected / exposed	8 / 8569 (0.09%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Mallory-Weiss syndrome		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin and subcutaneous tissue disorders</b>			
<b>Actinic keratosis</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Angioedema</b>			
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Decubitus ulcer</b>			
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dermal cyst</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dermatitis contact</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic bullosis</b>			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic foot</b>			
subjects affected / exposed	29 / 8569 (0.34%)	37 / 8574 (0.43%)	
occurrences causally related to treatment / all	0 / 34	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic ulcer</b>			

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema multiforme		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fixed eruption		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hidradenitis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypersensitivity vasculitis		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic skin ulcer		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keloid scar		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen planus		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen sclerosus		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melanocytic hyperplasia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic ulcer		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Purpura		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyoderma gangrenosum		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin swelling		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	23 / 8569 (0.27%)	24 / 8574 (0.28%)
occurrences causally related to treatment / all	0 / 26	1 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Stasis dermatitis		

subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic skin eruption			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch-Schonlein purpura			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	127 / 8569 (1.48%)	94 / 8574 (1.10%)	
occurrences causally related to treatment / all	21 / 152	10 / 96	
deaths causally related to treatment / all	1 / 6	1 / 4	
Azotaemia			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder disorder			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder perforation			

subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder mass		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder prolapse		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	6 / 8569 (0.07%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Calculus urinary		
subjects affected / exposed	4 / 8569 (0.05%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	13 / 8569 (0.15%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	1 / 17	1 / 10
deaths causally related to treatment / all	0 / 2	0 / 0
Cystitis glandularis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis noninfective		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis ulcerative		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	7 / 8569 (0.08%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	1 / 8	0 / 3
deaths causally related to treatment / all	1 / 3	0 / 0
Dysuria		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Glomerulonephritis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	16 / 8569 (0.19%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 19	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	6 / 8569 (0.07%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower urinary tract symptoms		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myeloma cast nephropathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ketonuria		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	18 / 8569 (0.21%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	0 / 18	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous kidney		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-ureteric obstruction		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pollakiuria		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	5 / 8569 (0.06%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst ruptured		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal disorder		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	17 / 8569 (0.20%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	1 / 17	2 / 11
deaths causally related to treatment / all	0 / 2	0 / 1
Renal haematoma		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	12 / 8569 (0.14%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	2 / 12	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal injury		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular acidosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular necrosis		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		

subjects affected / exposed	17 / 8569 (0.20%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	1 / 21	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral meatus stenosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral obstruction		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder haemorrhage		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder polyp		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		
subjects affected / exposed	10 / 8569 (0.12%)	8 / 8574 (0.09%)
occurrences causally related to treatment / all	1 / 10	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract obstruction		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endocrine disorders</b>			
<b>Adrenal insufficiency</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Adrenal mass</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Adrenomegaly</b>			
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Basedow's disease</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Goitre</b>			
subjects affected / exposed	8 / 8569 (0.09%)	7 / 8574 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperadrenalism</b>			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperparathyroidism</b>			
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypopituitarism</b>			

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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 / 8569 (0.01%)	0 / 8574 (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			
Arthritis			
subjects affected / exposed	9 / 8569 (0.11%)	14 / 8574 (0.16%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	2 / 8569 (0.02%)	7 / 8574 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Articular calcification			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	6 / 8569 (0.07%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	3 / 8569 (0.04%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	9 / 8569 (0.11%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Chondromalacia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chondropathy		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Compartment syndrome		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diastasis recti abdominis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		

subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extraskkeletal ossification		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facet joint syndrome		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fasciitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture malunion		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture nonunion		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc compression		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	6 / 8569 (0.07%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc displacement		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	17 / 8569 (0.20%)	24 / 8574 (0.28%)
occurrences causally related to treatment / all	0 / 18	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw cyst		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament calcification		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint ankylosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint contracture		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscal degeneration		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	18 / 8569 (0.21%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	0 / 18	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle fibrosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle haemorrhage</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscular weakness</b>		
subjects affected / exposed	6 / 8569 (0.07%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal chest pain</b>		
subjects affected / exposed	24 / 8569 (0.28%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 25	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal pain</b>		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuropathic arthropathy</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myositis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neck pain</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteochondrosis</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteitis</b>		
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoarthritis</b>		
subjects affected / exposed	92 / 8569 (1.07%)	103 / 8574 (1.20%)
occurrences causally related to treatment / all	0 / 102	1 / 114
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteonecrosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoporosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteolysis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoporotic fracture</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain in jaw</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Patellofemoral pain syndrome		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudarthrosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	4 / 8569 (0.05%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Rhabdomyolysis</b>		
subjects affected / exposed	7 / 8569 (0.08%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psoriatic arthropathy</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sjogren's syndrome</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal column stenosis</b>		
subjects affected / exposed	12 / 8569 (0.14%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rotator cuff syndrome</b>		
subjects affected / exposed	16 / 8569 (0.19%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 16	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal ligament ossification</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal osteoarthritis</b>		
subjects affected / exposed	3 / 8569 (0.04%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylolisthesis</b>		

subjects affected / exposed	5 / 8569 (0.06%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Tendonitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Trigger finger		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis stenosaurs		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertebral lesion</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Immunoglobulin G4 related disease</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal sepsis</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Abdominal wall abscess</b>			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abscess</b>			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abscess limb</b>			
subjects affected / exposed	9 / 8569 (0.11%)	8 / 8574 (0.09%)	
occurrences causally related to treatment / all	1 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acquired immunodeficiency syndrome</b>			

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute endocarditis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Amoebiasis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	5 / 8569 (0.06%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	12 / 8569 (0.14%)	12 / 8574 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		

subjects affected / exposed	11 / 8569 (0.13%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 13	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aspergilloma		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	3 / 8569 (0.04%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterascites		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial colitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial tracheitis		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteriuria</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Beta haemolytic streptococcal infection</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Biliary sepsis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Bone abscess</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain abscess</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast abscess</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		
subjects affected / exposed	35 / 8569 (0.41%)	15 / 8574 (0.17%)
occurrences causally related to treatment / all	0 / 35	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis bacterial</b>		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burn infection		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis infective		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	93 / 8569 (1.09%)	84 / 8574 (0.98%)
occurrences causally related to treatment / all	2 / 117	0 / 100
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis gangrenous		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis of male external genital organ		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis orbital		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system infection		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall abscess		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	3 / 8569 (0.04%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic sinusitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridial sepsis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Clostridium difficile colitis		
subjects affected / exposed	2 / 8569 (0.02%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		

subjects affected / exposed	1 / 8569 (0.01%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Cystitis</b>		
subjects affected / exposed	3 / 8569 (0.04%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 3	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cytomegalovirus viraemia</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dengue fever</b>		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic foot infection</b>		
subjects affected / exposed	13 / 8569 (0.15%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	0 / 13	1 / 11
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Device related infection</b>		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic gangrene</b>		
subjects affected / exposed	11 / 8569 (0.13%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diarrhoea infectious</b>		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diverticulitis</b>		

subjects affected / exposed	20 / 8569 (0.23%)	20 / 8574 (0.23%)
occurrences causally related to treatment / all	0 / 22	1 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Empyema		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis		
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 0
Encephalomyelitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Endocarditis bacterial		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endocarditis enterococcal		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis staphylococcal		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometritis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottitis		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		

subjects affected / exposed	13 / 8569 (0.15%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 13	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	0 / 8569 (0.00%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
External ear cellulitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural abscess		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal infection		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	30 / 8569 (0.35%)	22 / 8574 (0.26%)
occurrences causally related to treatment / all	0 / 40	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Gas gangrene		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric infection		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis</b>		
subjects affected / exposed	27 / 8569 (0.32%)	26 / 8574 (0.30%)
occurrences causally related to treatment / all	0 / 27	2 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis norovirus</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis rotavirus</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis salmonella</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis viral</b>		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Groin abscess</b>		
subjects affected / exposed	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Giardiasis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Helicobacter infection</b>		

subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma infection</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatitis viral</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Herpes zoster</b>		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Human anaplasmosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Implant site infection</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infected skin ulcer</b>		
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infection</b>		
subjects affected / exposed	6 / 8569 (0.07%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infectious colitis</b>		

subjects affected / exposed	2 / 8569 (0.02%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Infective gastroduodenitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	15 / 8569 (0.18%)	17 / 8574 (0.20%)
occurrences causally related to treatment / all	0 / 15	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.00%)	1 / 8574 (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	4 / 8569 (0.05%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Localised infection		
subjects affected / exposed	10 / 8569 (0.12%)	16 / 8574 (0.19%)
occurrences causally related to treatment / all	0 / 11	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	10 / 8569 (0.12%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malaria		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		

subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mediastinitis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical device site abscess</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical device site infection</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical device site joint infection</b>		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningitis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningitis aseptic</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningitis pneumococcal</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Meningitis viral</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mucormycosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle abscess</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Necrotising fasciitis</b>		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurosyphilis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neutropenic sepsis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal candidiasis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Onychomycosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oral candidiasis</b>		

subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orchitis</b>		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oropharyngeal candidiasis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis</b>		
subjects affected / exposed	39 / 8569 (0.46%)	26 / 8574 (0.30%)
occurrences causally related to treatment / all	1 / 46	0 / 35
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis acute</b>		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis chronic</b>		
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis externa</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media chronic</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatic abscess</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parainfluenzae virus infection</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parotitis</b>		
subjects affected / exposed	3 / 8569 (0.04%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic abscess</b>		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic inflammatory disease</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Perineal abscess</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Perinephric abscess</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periodontitis</b>		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	5 / 8569 (0.06%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Peritonitis bacterial		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy viral		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal infection		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumococcal sepsis		
subjects affected / exposed	0 / 8569 (0.00%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		

subjects affected / exposed	219 / 8569 (2.56%)	194 / 8574 (2.26%)
occurrences causally related to treatment / all	3 / 246	2 / 212
deaths causally related to treatment / all	1 / 21	0 / 10
Pneumonia bacterial		
subjects affected / exposed	5 / 8569 (0.06%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia respiratory syncytial viral		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural cellulitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		

subjects affected / exposed	5 / 8569 (0.06%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	1 / 8569 (0.01%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	13 / 8569 (0.15%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic abscess		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary tuberculosis		
subjects affected / exposed	3 / 8569 (0.04%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	14 / 8569 (0.16%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	9 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		

subjects affected / exposed	15 / 8569 (0.18%)	10 / 8574 (0.12%)
occurrences causally related to treatment / all	5 / 15	3 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal abscess		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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 bronchiolitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus bronchitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Retroperitoneal abscess		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rhinitis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rickettsiosis</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rotavirus infection</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Salmonella bacteraemia</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrotal abscess</b>		
subjects affected / exposed	4 / 8569 (0.05%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrub typhus</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sepsis</b>		
subjects affected / exposed	70 / 8569 (0.82%)	77 / 8574 (0.90%)
occurrences causally related to treatment / all	2 / 71	3 / 84
deaths causally related to treatment / all	0 / 10	0 / 14
<b>Sepsis syndrome</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Septic arthritis staphylococcal		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	24 / 8569 (0.28%)	21 / 8574 (0.24%)
occurrences causally related to treatment / all	1 / 27	0 / 22
deaths causally related to treatment / all	0 / 9	0 / 7
Sinusitis		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis fungal		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin bacterial infection		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic abscess		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	3 / 8569 (0.04%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	5 / 8569 (0.06%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal abscess		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	2 / 8569 (0.02%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tick-borne fever		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth infection		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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	2 / 8569 (0.02%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	5 / 8569 (0.06%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		

subjects affected / exposed	67 / 8569 (0.78%)	49 / 8574 (0.57%)
occurrences causally related to treatment / all	20 / 71	15 / 53
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	1 / 8569 (0.01%)	2 / 8574 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection enterococcal		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (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	25 / 8569 (0.29%)	22 / 8574 (0.26%)
occurrences causally related to treatment / all	9 / 26	9 / 23
deaths causally related to treatment / all	0 / 0	1 / 1
Vestibular neuronitis		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viraemia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	7 / 8569 (0.08%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 8	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Viral sinusitis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral myocarditis		

subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound abscess		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection pseudomonas		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	10 / 8569 (0.12%)	11 / 8574 (0.13%)
occurrences causally related to treatment / all	0 / 11	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1
Acute hepatitis B		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis C		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
H1N1 influenza		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HIV infection		

subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV-associated neurocognitive disorder			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			
subjects affected / exposed	0 / 8569 (0.00%)	2 / 8574 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
West Nile viral infection			
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (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			
Adult failure to thrive			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic ketoacidosis			
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	19 / 8569 (0.22%)	20 / 8574 (0.23%)
occurrences causally related to treatment / all	1 / 19	1 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Decreased appetite		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	13 / 8569 (0.15%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	1 / 13	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	29 / 8569 (0.34%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	2 / 34	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes with hyperosmolarity		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic complication		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (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	23 / 8569 (0.27%)	27 / 8574 (0.31%)
occurrences causally related to treatment / all	2 / 27	2 / 29
deaths causally related to treatment / all	1 / 2	0 / 0
Diabetic ketosis		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		

subjects affected / exposed	27 / 8569 (0.32%)	17 / 8574 (0.20%)
occurrences causally related to treatment / all	0 / 35	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Electrolyte imbalance</b>		
subjects affected / exposed	4 / 8569 (0.05%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Euglycaemic diabetic ketoacidosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Failure to thrive</b>		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gout</b>		
subjects affected / exposed	6 / 8569 (0.07%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fluid retention</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fluid overload</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypercalcaemia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperglycaemia</b>		

subjects affected / exposed	55 / 8569 (0.64%)	37 / 8574 (0.43%)
occurrences causally related to treatment / all	1 / 56	0 / 49
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	5 / 8569 (0.06%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	6 / 8569 (0.07%)	6 / 8574 (0.07%)
occurrences causally related to treatment / all	0 / 7	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperlipidaemia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypernatraemia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperuricaemia		
subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		

subjects affected / exposed	86 / 8569 (1.00%)	69 / 8574 (0.80%)
occurrences causally related to treatment / all	19 / 101	23 / 86
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Hypokalaemia</b>		
subjects affected / exposed	4 / 8569 (0.05%)	5 / 8574 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypomagnesaemia</b>		
subjects affected / exposed	1 / 8569 (0.01%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypovolaemia</b>		
subjects affected / exposed	4 / 8569 (0.05%)	14 / 8574 (0.16%)
occurrences causally related to treatment / all	1 / 4	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyponatraemia</b>		
subjects affected / exposed	9 / 8569 (0.11%)	9 / 8574 (0.10%)
occurrences causally related to treatment / all	0 / 9	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ketoacidosis</b>		
subjects affected / exposed	2 / 8569 (0.02%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 2	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ketosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lactic acidosis</b>		
subjects affected / exposed	3 / 8569 (0.04%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Latent autoimmune diabetes in adults</b>		

subjects affected / exposed	1 / 8569 (0.01%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malnutrition</b>		
subjects affected / exposed	2 / 8569 (0.02%)	0 / 8574 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lipomatosis</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Obesity</b>		
subjects affected / exposed	8 / 8569 (0.09%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic acidosis</b>		
subjects affected / exposed	3 / 8569 (0.04%)	3 / 8574 (0.03%)
occurrences causally related to treatment / all	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Type 1 diabetes mellitus</b>		
subjects affected / exposed	2 / 8569 (0.02%)	4 / 8574 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Type 2 diabetes mellitus</b>		
subjects affected / exposed	7 / 8569 (0.08%)	7 / 8574 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vitamin D deficiency</b>		
subjects affected / exposed	0 / 8569 (0.00%)	1 / 8574 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Placebo	Dapa 10 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	342 / 8569 (3.99%)	268 / 8574 (3.13%)	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	112 / 8569 (1.31%)	82 / 8574 (0.96%)	
occurrences (all)	129	91	
Renal impairment			
subjects affected / exposed	146 / 8569 (1.70%)	121 / 8574 (1.41%)	
occurrences (all)	159	126	
Chronic kidney disease			
subjects affected / exposed	104 / 8569 (1.21%)	77 / 8574 (0.90%)	
occurrences (all)	108	78	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 December 2013	Amendment #2 included implementation of a request from regulatory authorities to include further measurements and action to allow patients to continue study drug if creatinine clearance was found to be <60 ml/min during the study. With these measures added, patients could stay on study drug until creatinine clearance <30 ml/min as planned.
28 April 2014	Amendment #3 included implementation as per regulatory authorities' requirement to add hypersensitivity reactions (SAE/DAE), urinary tract infections (SAE/DAE), genital infections (SAE/DAE) and fractures to be recorded as AE of special interest.
25 September 2016	Amendment #5 included implementation as per regulatory authorities' requirements to add to adjudicate possible cases of diabetes ketoacidosis and collect additional information on cases of amputations.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported