

**Clinical trial results:****A Clinical Outcomes Study of Darapladib versus Placebo in Subjects with Chronic Coronary Heart Disease to Compare the Incidence of Major Adverse Cardiovascular Events (MACE)****Summary**

EudraCT number	2008-005575-96
Trial protocol	NL ES HU SE DE GB SK FR DK EE BE CZ PL BG IT GR
Global end of trial date	17 October 2013

**Results information**

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	11 April 2015

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

Sponsor protocol code	LPL100601
-----------------------	-----------

**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00799903
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 866 435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 866 435-7343,

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	02 December 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	17 October 2013
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate clinical efficacy of long-term treatment with darapladib Enteric Coated tablets, 160 mg (oral once daily dose) as compared to placebo when added to standard of care in a chronic Coronary Heart Disease (CHD) patient population on the incidence of first occurrence of the composite of Major Adverse Cardiovascular Events (MACE) (cardiovascular death, non-fatal Myocardial Infarction (MI), non-fatal stroke).

Protection of trial subjects:

The secreted isoform of Lp-PLA2 was first identified on the basis of its in vitro ability to degrade platelet-activating factor (PAF), hence it is also known as PAF-acetylhydrolase (PAF-AH). Although the assertion that Lp-PLA2 degrades PAF in vivo remains unproven, PAF has been implicated in prothrombotic, allergic and inflammatory responses, suggesting that blocking its degradation in patients may be detrimental. Due to this theoretical concern, participants with severe asthma poorly controlled on pharmacotherapy and participants with a history of anaphylaxis, anaphylactoid (resembling anaphylaxis) reactions, or severe allergic responses were excluded from participating in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 December 2008
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	Estonia: 77
Country: Number of subjects enrolled	France: 250
Country: Number of subjects enrolled	Germany: 1089
Country: Number of subjects enrolled	Greece: 187
Country: Number of subjects enrolled	Hungary: 410
Country: Number of subjects enrolled	Italy: 256
Country: Number of subjects enrolled	Netherlands: 444
Country: Number of subjects enrolled	Norway: 113
Country: Number of subjects enrolled	Poland: 510
Country: Number of subjects enrolled	Romania: 411
Country: Number of subjects enrolled	Slovakia: 120
Country: Number of subjects enrolled	Spain: 474
Country: Number of subjects enrolled	Sweden: 299
Country: Number of subjects enrolled	United Kingdom: 184
Country: Number of subjects enrolled	Belgium: 202

Country: Number of subjects enrolled	Bulgaria: 222
Country: Number of subjects enrolled	Czech Republic: 774
Country: Number of subjects enrolled	Denmark: 102
Country: Number of subjects enrolled	Argentina: 542
Country: Number of subjects enrolled	Australia: 306
Country: Number of subjects enrolled	Brazil: 384
Country: Number of subjects enrolled	Canada: 780
Country: Number of subjects enrolled	Chile: 195
Country: Number of subjects enrolled	China: 369
Country: Number of subjects enrolled	Hong Kong: 117
Country: Number of subjects enrolled	India: 398
Country: Number of subjects enrolled	Japan: 318
Country: Number of subjects enrolled	Korea, Republic of: 503
Country: Number of subjects enrolled	Mexico: 141
Country: Number of subjects enrolled	New Zealand: 202
Country: Number of subjects enrolled	Pakistan: 250
Country: Number of subjects enrolled	Peru: 78
Country: Number of subjects enrolled	Philippines: 219
Country: Number of subjects enrolled	Russian Federation: 654
Country: Number of subjects enrolled	South Africa: 386
Country: Number of subjects enrolled	Taiwan: 200
Country: Number of subjects enrolled	Thailand: 207
Country: Number of subjects enrolled	Ukraine: 353
Country: Number of subjects enrolled	United States: 3102
Worldwide total number of subjects	15828
EEA total number of subjects	6124

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	7701
From 65 to 84 years	8029
85 years and over	98

## Subject disposition

### Recruitment

Recruitment details:

The study consisted of a Screening Phase of up to 8 weeks duration, a Treatment Phase, an End-of-Treatment (EOT) visit, and a Follow-up visit scheduled for 35 +/- 7 days after last study drug intake. The median treatment duration was anticipated to be 2.75 years.

### Pre-assignment

Screening details:

During the Screening Phase of the study, participants presenting with chronic Coronary Heart Disease (CHD) were randomized within 8 weeks. In addition to chronic CHD, participants were required to have at least one additional predictor of cardiovascular risk specified in the protocol.

### Period 1

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

### Arms

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

Arm description:

Participants were randomized to receive matching placebo once daily.

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

Dosage and administration details:

enteric-coated, micronized, free-base tablet dosed once daily with food and swallowed whole (not crushed or chewed)

<b>Arm title</b>	Darapladib
------------------	------------

Arm description:

Participants were randomized to receive darapladib 160 milligram (mg) enteric-coated tablets once daily.

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

Dosage and administration details:

160 milligram (mg) enteric-coated, micronized, free-base tablet dosed once daily with food and swallowed whole (not crushed or chewed)

<b>Number of subjects in period 1</b>	Placebo	Darapladib
Started	7904	7924
Completed	7631	7646
Not completed	273	278
Consent withdrawn by subject	179	175
Investigator Site Closed	25	23
Lost to follow-up	69	80

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo
Reporting group description: Participants were randomized to receive matching placebo once daily.	
Reporting group title	Darapladib
Reporting group description: Participants were randomized to receive darapladib 160 milligram (mg) enteric-coated tablets once daily.	

Reporting group values	Placebo	Darapladib	Total
Number of subjects	7904	7924	15828
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	64.3	64.5	-
standard deviation	± 9.39	± 9.31	-
Gender categorical			
Units: Subjects			
Female	1506	1461	2967
Male	6398	6463	12861
Race, customized			
Units: Subjects			
White	6177	6233	12410
Japanese/East Asian (EA)/South EA Heritage (HER)	1017	1003	2020
Central/South Asian Heritage	347	347	694
Mixed Asian Heritage	2	1	3
African American (AA)/African Heritage (AH)	191	175	366
American Indian or Alaska Native	108	106	214
African American/African Heritage & White	36	37	73
American Indian or Alaska Native & White	12	11	23
Native Hawaiian or other Pacific Islander	11	4	15
AA/AH & American Indian or Alaska Native	2	1	3

Asian & White	0	3	3
Native Hawaiian or other Pacific Islander & White	0	2	2
African American/African Heritage & Asian	1	0	1
American Indian or Alaska Native & Asian	0	1	1

## End points

### End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants were randomized to receive matching placebo once daily.	
Reporting group title	Darapladib
Reporting group description:	
Participants were randomized to receive darapladib 160 milligram (mg) enteric-coated tablets once daily.	

### Primary: Number of participants with first occurrence of any component of the composite of major adverse cardiovascular events (cardiovascular [CV] death, non-fatal myocardial infarction [MI] or non-fatal stroke) during the time period for follow-up of CV events

End point title	Number of participants with first occurrence of any component of the composite of major adverse cardiovascular events (cardiovascular [CV] death, non-fatal myocardial infarction [MI] or non-fatal stroke) during the time period for follow-up of CV events
End point description:	
CV death=death due to a CV cause, which included but was not limited to deaths resulting from stroke, arrhythmia, sudden death (witnessed/unwitnessed), MI, heart failure, pulmonary embolism, peripheral arterial disease, or complications of a CV procedure. Deaths not clearly attributable to non-CV causes are considered to be CV deaths. Acute MI=evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required for verification of new abnormality), OR pathological findings of a healed/healing MI. Stroke=presence of a new focal neurologic deficit thought to be of vascular origin, with signs/symptoms lasting >24 hours or results in death (in <24 hours).	
End point type	Primary
End point timeframe:	
From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)	

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[1]</sup>	7924 <sup>[2]</sup>		
Units: participants	819	769		

Notes:

[1] - All Randomized (Intent-to-Treat [ITT]) Population: all randomized participants

[2] - All Randomized (Intent-to-Treat [ITT]) Population: all randomized participants

### Statistical analyses

Statistical analysis title	Statistical Analysis for Primary Endpoint
Comparison groups	Placebo v Darapladib

Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.199 [3]
Method	Cox proportional hazard regression model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95.1 %
sides	2-sided
lower limit	0.85
upper limit	1.03

Notes:

[3] - Statistical significance of this P-value was based on the alpha-spending function of this study.

**Secondary: Number of participants with first occurrence of any event in the composite of major coronary events (coronary heart disease [CHD] death, non-fatal MI, or urgent coronary revascularization [CR] for MI) during the time period for follow-up (FU) of CV events**

End point title	Number of participants with first occurrence of any event in the composite of major coronary events (coronary heart disease [CHD] death, non-fatal MI, or urgent coronary revascularization [CR] for MI) during the time period for follow-up (FU) of CV events
-----------------	---

End point description:

CHD death=occurrence of a fatal MI, death caused by documented cardiac arrest, death resulting from heart failure in a participant with known CHD, death from other forms of acute/chronic CHD, unwitnessed death of unknown origin, or sudden death. Acute MI=evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required for verification of new abnormality), OR pathological findings of a healed/healing MI. Urgent CR for MI=ischemic discomfort at rest that prompted CR (percutaneous coronary intervention [PCI: any attempt at CR even if not successful] or coronary artery bypass graft) during the same hospitalization or resulted in hospital transfer for the purpose of CR.

End point type	Secondary
----------------	-----------

End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[4]</sup>	7924 <sup>[5]</sup>		
Units: participants	814	737		

Notes:

[4] - All Randomized (ITT) Population

[5] - All Randomized (ITT) Population

**Statistical analyses**

Statistical analysis title	Statistical Analysis for Secondary Endpoint #1
Comparison groups	Placebo v Darapladib

Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045
Method	Cox proportional hazard regression model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1

**Secondary: Number of participants with first occurrence of any event in the composite of total coronary events (CHD death, non-fatal MI, hospitalization for unstable angina, or any coronary revascularization procedure) during time period for FU of CV events**

End point title	Number of participants with first occurrence of any event in the composite of total coronary events (CHD death, non-fatal MI, hospitalization for unstable angina, or any coronary revascularization procedure) during time period for FU of CV events
-----------------	--

End point description:

CHD death, acute MI, and prior MI are defined in the previous secondary endpoint (major coronary events). Hospitalization for unstable angina=one of the following, but not fulfilling the criteria for MI: ischemic discomfort at rest associated with electrocardiogram (ECG) changes leading to hospitalization; ischemic discomfort at rest regardless of ECG changes leading to hospitalization and revascularization during the same admission; ischemic discomfort at rest in hospital associated with ECG changes; ischemic discomfort at rest in hospital without ECG changes resulting in revascularization during the same admission. NOTE: The event was not considered to be unstable angina if, after invasive/non-invasive testing or other diagnostic testing, the discomfort is found not to be caused by myocardial ischemia.

End point type	Secondary
----------------	-----------

End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[6]</sup>	7924 <sup>[7]</sup>		
Units: participants	1269	1159		

Notes:

[6] - All Randomized (ITT) Population

[7] - All Randomized (ITT) Population

**Statistical analyses**

Statistical analysis title	Statistical Analysis for Secondary Endpoint #2
Comparison groups	Placebo v Darapladib

Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	0.98

### Secondary: Number of participants with CV death during the time period for follow-up of CV events

End point title	Number of participants with CV death during the time period for follow-up of CV events
-----------------	--

End point description:

CV death is defined as a death due to a CV cause, which included but was not limited to deaths resulting from stroke, arrhythmia, sudden death (witnessed/unwitnessed), MI, heart failure, pulmonary embolism, peripheral arterial disease, or complications of a CV procedure. Deaths not clearly attributable to non-CV causes are considered to be CV deaths.

End point type	Secondary
----------------	-----------

End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[8]</sup>	7924 <sup>[9]</sup>		
Units: participants	373	359		

Notes:

[8] - All Randomized (ITT) Population

[9] - All Randomized (ITT) Population

### Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis for Secondary Endpoint #3
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.594
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.11

### Secondary: Number of participants with first occurrence of MI (fatal/non-fatal) during the time period for follow-up of CV events

End point title	Number of participants with first occurrence of MI (fatal/non-fatal) during the time period for follow-up of CV events
-----------------	--

End point description:

Acute MI is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required for verification of new abnormality), OR pathological findings of a healed/healing MI.

End point type	Secondary
----------------	-----------

End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[10]</sup>	7924 <sup>[11]</sup>		
Units: participants	405	361		

Notes:

[10] - All Randomized (ITT) Population

[11] - All Randomized (ITT) Population

### Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis for Secondary Endpoint #4
Comparison groups	Darapladib v Placebo
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.108
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.03

**Secondary: Number of participants with first occurrence of stroke (fatal/non-fatal) during the time period for follow-up of CV events**

End point title	Number of participants with first occurrence of stroke (fatal/non-fatal) during the time period for follow-up of CV events
End point description: Stroke is defined as the presence of a new focal neurologic deficit thought to be of vascular origin, with signs/symptoms lasting >24 hours or results in death (in <24 hours).	
End point type	Secondary
End point timeframe: From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)	

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[12]</sup>	7924 <sup>[13]</sup>		
Units: participants	152	154		

Notes:

[12] - All Randomized (ITT) Population

[13] - All Randomized (ITT) Population

**Statistical analyses**

<b>Statistical analysis title</b>	Statistical Analysis for Secondary Endpoint #5
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.92
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.27

**Secondary: Number of participants with first occurrence of any component of the composite of all-cause mortality, non-fatal MI, or non-fatal stroke during the time period for follow-up of CV events**

End point title	Number of participants with first occurrence of any component of the composite of all-cause mortality, non-fatal MI, or non-fatal stroke during the time period for follow-up of CV events
End point description: Acute MI is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required	

for verification of new abnormality), OR pathological findings of a healed/healing MI. Stroke=presence of a new focal neurologic deficit thought to be of vascular origin, with signs/symptoms lasting >24 hours or results in death (in <24 hours).

End point type	Secondary
----------------	-----------

End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

<b>End point values</b>	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[14]</sup>	7924 <sup>[15]</sup>		
Units: participants	962	926		

Notes:

[14] - All Randomized (ITT) Population

[15] - All Randomized (ITT) Population

### Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis for Secondary Endpoint #6
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.397
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.05

### Secondary: Number of participants with all-cause mortality during the time period for vital status

End point title	Number of participants with all-cause mortality during the time period for vital status
-----------------	---

End point description:

The number of participants with all-cause mortality was assessed.

End point type	Secondary
----------------	-----------

End point timeframe:

From randomization until death or study completion (up to 4.49 years/average of 3.65 years)

<b>End point values</b>	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 <sup>[16]</sup>	7924 <sup>[17]</sup>		
Units: participants	577	582		

Notes:

[16] - All Randomized (ITT) Population

[17] - All Randomized (ITT) Population

### Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis for Secondary Endpoint #7
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.87
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.13

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Start=Randomization; Stop=Longer of 35 days after last dose of IP or follow-up (FU) visit. "SAEs assessed as related to IP, study participation, or a GSK concomitant medication" and cancer/GI polyps/neoplasms were recorded up to/including any FU contact.

Adverse event reporting additional description:

SAEs and non-serious AEs were collected in members of the Safety Population, comprised of all randomized participants who received at least one dose of investigational product. Post-randomization AEs have an onset date that is on or after the randomization date.

Assessment type	Systematic
-----------------	------------

### Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	16.0
--------------------	------

### Reporting groups

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

Participants received matching placebo once daily.

Reporting group title	Darapladib
-----------------------	------------

Reporting group description:

Participants received darapladib 160 milligram (mg) enteric-coated tablets once daily.

<b>Serious adverse events</b>	Placebo	Darapladib	
Total subjects affected by serious adverse events			
subjects affected / exposed	3448 / 7890 (43.70%)	3369 / 7912 (42.58%)	
number of deaths (all causes)	577	582	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lymphocytic leukaemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Acute myeloid leukaemia			

subjects affected / exposed	0 / 7890 (0.00%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 5
Adenocarcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Adenocarcinoma gastric		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	4 / 7890 (0.05%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	1 / 4	4 / 11
deaths causally related to treatment / all	0 / 1	1 / 1
Adenocarcinoma pancreas		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Adenoid cystic carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenocortical carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ameloblastoma		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anaplastic astrocytoma</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Angiosarcoma</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>B-cell lymphoma</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Basal cell carcinoma</b>		
subjects affected / exposed	8 / 7890 (0.10%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Benign anorectal neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Benign breast neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Benign hepatic neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Benign lung neoplasm</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign ovarian tumour		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct adenocarcinoma		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct cancer		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	1 / 2
Bladder cancer		
subjects affected / exposed	19 / 7890 (0.24%)	21 / 7912 (0.27%)
occurrences causally related to treatment / all	1 / 20	1 / 25
deaths causally related to treatment / all	0 / 1	0 / 2
Bladder cancer recurrent		

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder neoplasm</b>		
subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder papilloma</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder transitional cell carcinoma</b>		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone cancer</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Bone cancer metastatic</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Bowen's disease</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain cancer metastatic</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain neoplasm</b>		

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Brain neoplasm benign</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Brain neoplasm malignant</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer</b>		
subjects affected / exposed	7 / 7890 (0.09%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer metastatic</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer stage I</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchial carcinoma</b>		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1
<b>Cancer pain</b>		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour of the duodenum		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour of the gastrointestinal tract		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac myxoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	3 / 7890 (0.04%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Cholesteatoma		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chondrosarcoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.00%)	1 / 7912 (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	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic lymphocytic leukaemia stage 0		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	32 / 7890 (0.41%)	21 / 7912 (0.27%)
occurrences causally related to treatment / all	0 / 33	1 / 22
deaths causally related to treatment / all	0 / 5	0 / 6
Colon cancer metastatic		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Colon cancer stage 0		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer stage II		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endometrial adenocarcinoma		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Endometrial cancer		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer metastatic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gallbladder cancer		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Gastric adenoma		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	10 / 7890 (0.13%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	2 / 10	0 / 10
deaths causally related to treatment / all	1 / 6	0 / 6
Gastric cancer recurrent		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal stromal cancer		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Glioma		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Glottis carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.00%)	1 / 7912 (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	6 / 7890 (0.08%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 3
Hepatic cancer metastatic		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 1
Hepatic neoplasm		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Hypopharyngeal cancer		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypopharyngeal cancer recurrent		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal papillary-mucinous carcinoma of pancreas		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive lobular breast carcinoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine benign neoplasm		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	1 / 7890 (0.01%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Laryngeal cancer recurrent		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyosarcoma		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo maligna		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukaemia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lip and/or oral cavity cancer		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip neoplasm malignant stage unspecified		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	3 / 7890 (0.04%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 3	2 / 7
deaths causally related to treatment / all	0 / 0	1 / 3
Lung adenocarcinoma metastatic		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung adenocarcinoma stage II		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage IV		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	7 / 7890 (0.09%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 5	0 / 4
Lung carcinoma cell type unspecified recurrent		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung carcinoma cell type unspecified stage III		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm malignant		
subjects affected / exposed	37 / 7890 (0.47%)	33 / 7912 (0.42%)
occurrences causally related to treatment / all	0 / 38	0 / 33
deaths causally related to treatment / all	0 / 19	0 / 19
Lung squamous cell carcinoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphangiosis carcinomatosa		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lymphocytic lymphoma		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Malignant melanoma		
subjects affected / exposed	3 / 7890 (0.04%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant melanoma in situ		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 ampulla of Vater		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Malignant palate neoplasm		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant peritoneal neoplasm		

subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Mantle cell lymphoma</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Mediastinum neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Meningioma</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningioma benign</b>		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesothelioma</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to abdominal cavity</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Metastases to adrenals</b>		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Metastases to biliary tract</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Metastases to bone</b>		
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 4
<b>Metastases to central nervous system</b>		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 0
<b>Metastases to liver</b>		
subjects affected / exposed	9 / 7890 (0.11%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 5	0 / 3
<b>Metastases to lung</b>		
subjects affected / exposed	7 / 7890 (0.09%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 5	0 / 1
<b>Metastases to lymph nodes</b>		
subjects affected / exposed	7 / 7890 (0.09%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 3
<b>Metastases to peritoneum</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 pleura</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Metastases to spine</b>		

subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Metastases to the mediastinum		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Metastatic bronchial carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic carcinoma of the bladder		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic lymphoma		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic malignant melanoma		
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Metastatic neoplasm		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Metastatic salivary gland cancer		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic squamous cell carcinoma		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Morton's neuroma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	2 / 3	0 / 4
deaths causally related to treatment / all	1 / 1	0 / 0
Neoplasm malignant		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Neoplasm prostate		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurilemmoma benign		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		

subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 4
Non-small cell lung cancer metastatic		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	1 / 1
Oesophageal carcinoma		
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 3
Optic nerve neoplasm		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	8 / 7890 (0.10%)	17 / 7912 (0.21%)
occurrences causally related to treatment / all	2 / 8	0 / 17
deaths causally related to treatment / all	2 / 6	0 / 11
Pancreatic carcinoma metastatic		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papilloma		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Penile cancer		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal carcinoma metastatic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pheochromocytoma malignant		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pituitary tumour benign		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
Pleural mesothelioma		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Polycythaemia vera		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	64 / 7890 (0.81%)	67 / 7912 (0.85%)
occurrences causally related to treatment / all	1 / 64	1 / 67
deaths causally related to treatment / all	0 / 4	0 / 4
Prostate cancer metastatic		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 3
Prostate cancer recurrent		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal cancer		
subjects affected / exposed	10 / 7890 (0.13%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 14	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Rectosigmoid cancer		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Renal cancer</b>		
subjects affected / exposed	6 / 7890 (0.08%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Renal cancer metastatic</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Renal cell carcinoma</b>		
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3
<b>Renal neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Salivary gland adenoma</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Salivary gland neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sarcoma</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Signet-ring cell carcinoma</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 2
Small cell lung cancer metastatic		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small intestine adenocarcinoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Soft tissue cancer		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular malignant teratoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat cancer			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thymoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			

subjects affected / exposed	4 / 7890 (0.05%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	1 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tumour haemorrhage</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tumour invasion</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ureteral neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Ureteric cancer</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary bladder adenoma</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary tract neoplasm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Uterine cancer</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Uterine leiomyoma</b>		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures with secondary generalisation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm ruptured			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Angiopathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	24 / 7890 (0.30%)	35 / 7912 (0.44%)	
occurrences causally related to treatment / all	0 / 25	0 / 38	
deaths causally related to treatment / all	0 / 0	0 / 2	
Aortic aneurysm rupture			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Aortic arteriosclerosis			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic calcification		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dilatation		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Aortic stenosis		
subjects affected / exposed	15 / 7890 (0.19%)	16 / 7912 (0.20%)
occurrences causally related to treatment / all	0 / 15	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
Aortic thrombosis		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial disorder		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial insufficiency		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial rupture		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial stenosis		
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	6 / 7890 (0.08%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 3
Arteriovenous fistula		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Artery dissection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure fluctuation		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	10 / 7890 (0.13%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 3	0 / 0
Deep vein thrombosis		
subjects affected / exposed	17 / 7890 (0.22%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	1 / 17	2 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Embolism		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism venous		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extravasation blood		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Femoral artery aneurysm		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery occlusion		

subjects affected / exposed	12 / 7890 (0.15%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 15	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematocoele</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma</b>		
subjects affected / exposed	13 / 7890 (0.16%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 13	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemorrhage</b>		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Hypertension</b>		
subjects affected / exposed	32 / 7890 (0.41%)	29 / 7912 (0.37%)
occurrences causally related to treatment / all	3 / 34	0 / 33
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive crisis</b>		
subjects affected / exposed	16 / 7890 (0.20%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	1 / 16	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive emergency</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoperfusion</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypotension</b>		

subjects affected / exposed	39 / 7890 (0.49%)	27 / 7912 (0.34%)
occurrences causally related to treatment / all	0 / 41	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 2
Hypovolaemic shock		
subjects affected / exposed	2 / 7890 (0.03%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 5
Iliac artery occlusion		
subjects affected / exposed	7 / 7890 (0.09%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery rupture		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infarction		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intermittent claudication		
subjects affected / exposed	28 / 7890 (0.35%)	21 / 7912 (0.27%)
occurrences causally related to treatment / all	0 / 35	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic limb pain		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphocele		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypertension		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	8 / 7890 (0.10%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic venous thrombosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	55 / 7890 (0.70%)	46 / 7912 (0.58%)
occurrences causally related to treatment / all	1 / 68	0 / 54
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	2 / 7890 (0.03%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	21 / 7890 (0.27%)	23 / 7912 (0.29%)
occurrences causally related to treatment / all	0 / 34	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		

subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral embolism		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	20 / 7890 (0.25%)	19 / 7912 (0.24%)
occurrences causally related to treatment / all	0 / 26	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral vascular disorder		
subjects affected / exposed	27 / 7890 (0.34%)	24 / 7912 (0.30%)
occurrences causally related to treatment / all	0 / 29	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 1
Phlebitis		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis superficial		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Poor peripheral circulation		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renovascular hypertension		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Subclavian artery aneurysm		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery occlusion		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian steal syndrome		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Temporal arteritis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thromboangiitis obliterans		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	3 / 7890 (0.04%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	3 / 7890 (0.04%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein ruptured		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular insufficiency		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Venous insufficiency		

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous stenosis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Coronary revascularisation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	15 / 7890 (0.19%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 17	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 2	
Axillary pain			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac complication associated with device		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest discomfort		
subjects affected / exposed	7 / 7890 (0.09%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	18 / 7890 (0.23%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 18	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 2
Chills		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	73 / 7890 (0.93%)	56 / 7912 (0.71%)
occurrences causally related to treatment / all	1 / 73	0 / 56
deaths causally related to treatment / all	1 / 73	0 / 56
Device battery issue		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device dislocation		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Device lead damage		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device lead issue		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device malfunction		
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Device occlusion		
subjects affected / exposed	11 / 7890 (0.14%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	1 / 11	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Device power source issue		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drowning		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Face oedema		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fat necrosis		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fatigue</b>		
subjects affected / exposed	9 / 7890 (0.11%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	1 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gait disturbance</b>		
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>General physical health deterioration</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Generalised oedema</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hernia</b>		
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypothermia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ill-defined disorder</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Impaired healing</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Implant site thrombosis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inflammation</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Influenza like illness</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic ulcer</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lipogranuloma</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malaise</b>		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical device complication</b>		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical device pain</b>		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site reaction		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ disorder		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Multi-organ failure		
subjects affected / exposed	6 / 7890 (0.08%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 6	0 / 6
Nodule		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	196 / 7890 (2.48%)	191 / 7912 (2.41%)
occurrences causally related to treatment / all	0 / 235	1 / 238
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	6 / 7890 (0.08%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyp		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Puncture site haemorrhage		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	12 / 7890 (0.15%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	0 / 14	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 1
Spinal pain		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stent embolisation		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	22 / 7890 (0.28%)	24 / 7912 (0.30%)
occurrences causally related to treatment / all	0 / 22	0 / 24
deaths causally related to treatment / all	0 / 22	0 / 24
Sudden death		
subjects affected / exposed	56 / 7890 (0.71%)	57 / 7912 (0.72%)
occurrences causally related to treatment / all	0 / 56	1 / 57
deaths causally related to treatment / all	0 / 56	1 / 57
Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis in device		

subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibulitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergic oedema			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to arthropod bite			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to arthropod sting			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food allergy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Social circumstances</b>			
<b>Disability</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acquired phimosis</b>			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	28 / 7890 (0.35%)	31 / 7912 (0.39%)	
occurrences causally related to treatment / all	0 / 28	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Breast enlargement</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endometrial hyperplasia</b>			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Epididymal cyst			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital pain			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian mass			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fluid collection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile swelling			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peyronie's disease			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic disorder		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic obstruction		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatism		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	4 / 7890 (0.05%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatomegaly		
subjects affected / exposed	8 / 7890 (0.10%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal oedema		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal swelling		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal polyp			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute lung injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	14 / 7890 (0.18%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 15	0 / 13	
deaths causally related to treatment / all	0 / 4	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			

subjects affected / exposed	18 / 7890 (0.23%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	0 / 18	0 / 12
deaths causally related to treatment / all	0 / 4	0 / 2
Apnoea		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Asphyxia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Asthma		
subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0
Atelectasis		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial hyperreactivity		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Bronchitis chronic		

subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopleural fistula			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchopulmonary disease			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Chronic obstructive pulmonary disease			
subjects affected / exposed	52 / 7890 (0.66%)	50 / 7912 (0.63%)	
occurrences causally related to treatment / all	0 / 74	0 / 75	
deaths causally related to treatment / all	0 / 3	0 / 3	
Chronic respiratory failure			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cough			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic paralysis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphonia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	39 / 7890 (0.49%)	52 / 7912 (0.66%)
occurrences causally related to treatment / all	0 / 42	0 / 55
deaths causally related to treatment / all	0 / 0	0 / 2
Dyspnoea exertional		
subjects affected / exposed	7 / 7890 (0.09%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	1 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	6 / 7890 (0.08%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	6 / 7890 (0.08%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Haemothorax		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydropneumothorax		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	5 / 7890 (0.06%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Increased upper airway secretion		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Laryngeal cyst		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal oedema		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngospasm		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung consolidation		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung cyst		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Lung infiltration		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal haemorrhage		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal cyst		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal mucosal hypertrophy		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal turbinate hypertrophy		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Organising pneumonia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal pain		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthopnoea		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Painful respiration		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal oedema		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	20 / 7890 (0.25%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	0 / 22	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Pleuritic pain		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 4	0 / 0
Pneumonitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	6 / 7890 (0.08%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Productive cough		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary arterial hypertension		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary congestion</b>		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary embolism</b>		
subjects affected / exposed	26 / 7890 (0.33%)	35 / 7912 (0.44%)
occurrences causally related to treatment / all	1 / 29	1 / 35
deaths causally related to treatment / all	0 / 3	0 / 7
<b>Pulmonary fibrosis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pulmonary haemorrhage</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pulmonary hypertension</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pulmonary mass</b>		
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pulmonary oedema</b>		
subjects affected / exposed	15 / 7890 (0.19%)	17 / 7912 (0.21%)
occurrences causally related to treatment / all	0 / 15	1 / 17
deaths causally related to treatment / all	0 / 1	0 / 4
<b>Respiratory arrest</b>		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory disorder		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Respiratory failure		
subjects affected / exposed	24 / 7890 (0.30%)	18 / 7912 (0.23%)
occurrences causally related to treatment / all	0 / 25	0 / 18
deaths causally related to treatment / all	0 / 10	0 / 3
Restrictive pulmonary disease		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Sleep apnoea syndrome		
subjects affected / exposed	6 / 7890 (0.08%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Snoring		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status asthmaticus		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord thickening		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Aggression			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 2
Confusional state		
subjects affected / exposed	12 / 7890 (0.15%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Conversion disorder		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	4 / 7890 (0.05%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	7 / 7890 (0.09%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 8	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disorientation		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysthymic disorder		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Emotional distress</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hallucination</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hallucination, auditory</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Impulse-control disorder</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Insomnia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Major depression</b>		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mania</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental disorder</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental status changes</b>		
subjects affected / exposed	6 / 7890 (0.08%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Panic attack</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psychogenic seizure</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psychotic disorder</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sleep disorder</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Somatoform disorder cardiovascular</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Suicidal behaviour</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Suicidal ideation</b>		

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic liver disease			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bile duct obstruction			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	3 / 7890 (0.04%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary fistula			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	24 / 7890 (0.30%)	21 / 7912 (0.27%)
occurrences causally related to treatment / all	0 / 25	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	24 / 7890 (0.30%)	19 / 7912 (0.24%)
occurrences causally related to treatment / all	0 / 24	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 1
Cholecystitis chronic		
subjects affected / exposed	7 / 7890 (0.09%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	28 / 7890 (0.35%)	30 / 7912 (0.38%)
occurrences causally related to treatment / all	0 / 29	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis obstructive		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder disorder		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder pain		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic cyst		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Hepatic function abnormal		

subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	1 / 2	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic haemorrhage		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatitis alcoholic		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis toxic		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular injury		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatorenal failure		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatotoxicity		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocholecystis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperbilirubinaemia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic hepatitis		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Jaundice		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Liver injury		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumobilia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase abnormal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	11 / 7890 (0.14%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	1 / 11	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase abnormal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase			

increased			
subjects affected / exposed	6 / 7890 (0.08%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	1 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile output abnormal			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose decreased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure decreased		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urea increased		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urine present		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac murmur		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid bruit		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ECG signs of myocardial ischaemia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment depression		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate decreased		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate increased		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate irregular		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme abnormal		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	5 / 7890 (0.06%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	1 / 5	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased5		
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	2 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intraocular pressure increased		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test abnormal		
subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	1 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
Occult blood positive		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oxygen saturation decreased		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic specific antigen increased		

subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Red blood cell sedimentation rate increased		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scan myocardial perfusion abnormal		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcus test positive		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stroke volume decreased		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transaminases increased		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin I increased		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin increased		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		

subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bilirubin conjugated increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accident at home			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			

subjects affected / exposed	7 / 7890 (0.09%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arterial injury</b>		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Arterial restenosis</b>		
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arteriovenous fistula thrombosis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthropod sting</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Back injury</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone contusion</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain contusion</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Burns first degree</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Burns second degree</b>		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac function disturbance postoperative</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Cardiac procedure complication</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 restenosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chest injury</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Clavicle fracture</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Comminuted fracture</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Concussion</b>		

subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Contusion</b>		
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary artery restenosis</b>		
subjects affected / exposed	28 / 7890 (0.35%)	19 / 7912 (0.24%)
occurrences causally related to treatment / all	0 / 31	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Craniocerebral injury</b>		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Eschar</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Excoriation</b>		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Extradural haematoma</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Eye injury</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Eye penetration</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Face injury		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	17 / 7890 (0.22%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 17	0 / 11
deaths causally related to treatment / all	0 / 2	0 / 1
Femoral neck fracture		
subjects affected / exposed	12 / 7890 (0.15%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	11 / 7890 (0.14%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	0 / 11	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 1
Fibula fracture		
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder postoperative		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stoma complication		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Graft thrombosis		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gun shot wound		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		

subjects affected / exposed	11 / 7890 (0.14%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Heart injury</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hip fracture</b>		
subjects affected / exposed	10 / 7890 (0.13%)	13 / 7912 (0.16%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Humerus fracture</b>		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incision site haematoma</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incision site haemorrhage</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incisional hernia</b>		
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incisional hernia, obstructive</b>		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inflammation of wound</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Injury</b>		
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Internal injury</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc injury</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Jaw fracture</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint dislocation</b>		
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint injury</b>		
subjects affected / exposed	3 / 7890 (0.04%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Kidney contusion</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laceration</b>		

subjects affected / exposed	9 / 7890 (0.11%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament injury		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Liver contusion		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		

subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar vertebral fracture</b>		
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meniscus injury</b>		
subjects affected / exposed	8 / 7890 (0.10%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental status changes postoperative</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple fractures</b>		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple injuries</b>		
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle rupture</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle strain</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Overdose</b>		

subjects affected / exposed	5 / 7890 (0.06%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Patella fracture		
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	5 / 7890 (0.06%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Periprosthetic fracture		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perirenal haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post laminectomy syndrome		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Post procedural fistula		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	4 / 7890 (0.05%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural myocardial infarction		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural stroke		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural swelling		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative hernia		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Postoperative respiratory failure		

subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Postoperative thoracic procedure complication		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thrombosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural headache		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypotension		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural nausea		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural vomiting		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary contusion		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	5 / 7890 (0.06%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haematoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	9 / 7890 (0.11%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	6 / 7890 (0.08%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Shunt stenosis		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skull fracture</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skull fractured base</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Soft tissue injury</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal column injury</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal compression fracture</b>		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal fracture</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splenic rupture</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splinter</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	8 / 7890 (0.10%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	0 / 10	1 / 16
deaths causally related to treatment / all	0 / 2	0 / 5
Subdural haemorrhage		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Suture related complication		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial rupture		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	8 / 7890 (0.10%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular injury		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	6 / 7890 (0.08%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
Transfusion reaction		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transplant failure		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic renal injury		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ulna fracture		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder rupture		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular bypass dysfunction		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	6 / 7890 (0.08%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 7	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	8 / 7890 (0.10%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 11	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft thrombosis		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular procedure complication		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Venomous sting		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound evisceration		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound haematoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound necrosis		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Congenital, familial and genetic disorders</b>			
Arteriovenous malformation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal vessel congenital anomaly			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syringomyelia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
Acute coronary syndrome			
subjects affected / exposed	17 / 7890 (0.22%)	17 / 7912 (0.21%)	
occurrences causally related to treatment / all	0 / 19	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 2	
Acute left ventricular failure			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Acute myocardial infarction		
subjects affected / exposed	359 / 7890 (4.55%)	303 / 7912 (3.83%)
occurrences causally related to treatment / all	7 / 425	9 / 357
deaths causally related to treatment / all	1 / 44	1 / 35
Angina pectoris		
subjects affected / exposed	271 / 7890 (3.43%)	248 / 7912 (3.13%)
occurrences causally related to treatment / all	0 / 309	0 / 282
deaths causally related to treatment / all	0 / 3	0 / 0
Angina unstable		
subjects affected / exposed	489 / 7890 (6.20%)	472 / 7912 (5.97%)
occurrences causally related to treatment / all	8 / 618	2 / 569
deaths causally related to treatment / all	0 / 6	0 / 4
Aortic valve disease		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease mixed		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	10 / 7890 (0.13%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Arrhythmia		
subjects affected / exposed	8 / 7890 (0.10%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 2
Arrhythmia supraventricular		

subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	15 / 7890 (0.19%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 15	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1
Arteriospasm coronary		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	135 / 7890 (1.71%)	123 / 7912 (1.55%)
occurrences causally related to treatment / all	2 / 164	0 / 153
deaths causally related to treatment / all	0 / 2	0 / 0
Atrial flutter		
subjects affected / exposed	27 / 7890 (0.34%)	27 / 7912 (0.34%)
occurrences causally related to treatment / all	0 / 36	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	1 / 7890 (0.01%)	56 / 7912 (0.71%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	9 / 7890 (0.11%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		

subjects affected / exposed	12 / 7890 (0.15%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	7 / 7890 (0.09%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular dissociation		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bifascicular block		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	19 / 7890 (0.24%)	24 / 7912 (0.30%)
occurrences causally related to treatment / all	0 / 19	1 / 25
deaths causally related to treatment / all	0 / 1	0 / 1
Bundle branch block left		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block right		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac aneurysm</b>		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac arrest</b>		
subjects affected / exposed	26 / 7890 (0.33%)	28 / 7912 (0.35%)
occurrences causally related to treatment / all	0 / 26	0 / 28
deaths causally related to treatment / all	0 / 20	0 / 22
<b>Cardiac asthma</b>		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac discomfort</b>		
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	1 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac disorder</b>		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cardiac failure</b>		
subjects affected / exposed	178 / 7890 (2.26%)	155 / 7912 (1.96%)
occurrences causally related to treatment / all	2 / 244	3 / 225
deaths causally related to treatment / all	1 / 36	0 / 26
<b>Cardiac failure acute</b>		
subjects affected / exposed	16 / 7890 (0.20%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	1 / 16	0 / 12
deaths causally related to treatment / all	1 / 8	0 / 2
<b>Cardiac failure chronic</b>		

subjects affected / exposed	19 / 7890 (0.24%)	17 / 7912 (0.21%)
occurrences causally related to treatment / all	1 / 21	0 / 21
deaths causally related to treatment / all	0 / 5	0 / 2
Cardiac failure congestive		
subjects affected / exposed	135 / 7890 (1.71%)	125 / 7912 (1.58%)
occurrences causally related to treatment / all	2 / 196	1 / 168
deaths causally related to treatment / all	0 / 13	0 / 9
Cardiac tamponade		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve disease		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	15 / 7890 (0.19%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	1 / 15	1 / 15
deaths causally related to treatment / all	1 / 14	1 / 15
Cardiogenic shock		
subjects affected / exposed	11 / 7890 (0.14%)	16 / 7912 (0.20%)
occurrences causally related to treatment / all	0 / 11	0 / 16
deaths causally related to treatment / all	0 / 3	0 / 10
Cardiomyopathy		
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiopulmonary failure		
subjects affected / exposed	2 / 7890 (0.03%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 5
Cardiovascular deconditioning		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular disorder		
subjects affected / exposed	6 / 7890 (0.08%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 3
Cardiovascular insufficiency		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1
Chronic left ventricular failure		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronotropic incompetence		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Conduction disorder		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cor pulmonale chronic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		

subjects affected / exposed	177 / 7890 (2.24%)	168 / 7912 (2.12%)
occurrences causally related to treatment / all	0 / 190	0 / 185
deaths causally related to treatment / all	0 / 6	0 / 2
Coronary artery insufficiency		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Coronary artery occlusion		
subjects affected / exposed	17 / 7890 (0.22%)	19 / 7912 (0.24%)
occurrences causally related to treatment / all	1 / 17	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	59 / 7890 (0.75%)	56 / 7912 (0.71%)
occurrences causally related to treatment / all	3 / 64	0 / 59
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic dysfunction		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive cardiomyopathy		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intracardiac thrombus		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	14 / 7890 (0.18%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1
Left ventricular dysfunction		
subjects affected / exposed	8 / 7890 (0.10%)	13 / 7912 (0.16%)
occurrences causally related to treatment / all	0 / 8	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Left ventricular failure		
subjects affected / exposed	6 / 7890 (0.08%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 2	0 / 2
Left ventricular hypertrophy		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve disease		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	9 / 7890 (0.11%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve stenosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial fibrosis		

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Myocardial infarction</b>		
subjects affected / exposed	54 / 7890 (0.68%)	56 / 7912 (0.71%)
occurrences causally related to treatment / all	1 / 55	1 / 56
deaths causally related to treatment / all	0 / 21	1 / 34
<b>Myocardial ischaemia</b>		
subjects affected / exposed	41 / 7890 (0.52%)	47 / 7912 (0.59%)
occurrences causally related to treatment / all	0 / 45	0 / 49
deaths causally related to treatment / all	0 / 2	0 / 2
<b>Myocarditis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal arrhythmia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Palpitations</b>		
subjects affected / exposed	9 / 7890 (0.11%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial effusion</b>		
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial haemorrhage</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericarditis</b>		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis constrictive		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postinfarction angina		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Right ventricular failure		
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Sick sinus syndrome		
subjects affected / exposed	24 / 7890 (0.30%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	0 / 24	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Silent myocardial infarction		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial block		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrhythmia		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachyarrhythmia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		

subjects affected / exposed	8 / 7890 (0.10%)	14 / 7912 (0.18%)
occurrences causally related to treatment / all	0 / 11	3 / 16
deaths causally related to treatment / all	0 / 0	0 / 1
Systolic dysfunction		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Torsade de pointes		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve disease		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Ventricular dyssynchrony		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular extrasystoles		

subjects affected / exposed	9 / 7890 (0.11%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	19 / 7890 (0.24%)	22 / 7912 (0.28%)	
occurrences causally related to treatment / all	0 / 23	0 / 23	
deaths causally related to treatment / all	0 / 7	0 / 5	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	42 / 7890 (0.53%)	37 / 7912 (0.47%)	
occurrences causally related to treatment / all	1 / 56	1 / 41	
deaths causally related to treatment / all	0 / 2	1 / 3	
Congenital coronary artery malformation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	5 / 7890 (0.06%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Alcoholic seizure			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			

subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Aphasia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ataxia</b>		
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Balance disorder</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Basal ganglia infarction</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain injury</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Brain midline shift</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain oedema</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Brain stem haemorrhage</b>		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Brain stem infarction</b>		
subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Brain stem ischaemia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain stem stroke</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Carotid arteriosclerosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery disease</b>		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery occlusion</b>		
subjects affected / exposed	7 / 7890 (0.09%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery stenosis</b>		
subjects affected / exposed	47 / 7890 (0.60%)	48 / 7912 (0.61%)
occurrences causally related to treatment / all	0 / 51	0 / 54
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carpal tunnel syndrome</b>		

subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda equina syndrome		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system lesion		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar haemorrhage		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic mononeuropathy		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Disturbance in attention		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		

subjects affected / exposed	18 / 7890 (0.23%)	18 / 7912 (0.23%)
occurrences causally related to treatment / all	1 / 18	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 1
Dizziness exertional		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysaesthesia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyslalia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dystonia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic cerebral infarction		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		

subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Encephalitis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Encephalomalacia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Encephalopathy</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epilepsy</b>		
subjects affected / exposed	5 / 7890 (0.06%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	1 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Facial paresis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Grand mal convulsion</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Guillain-Barre syndrome</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemorrhage intracranial</b>		

subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Haemorrhagic cerebral infarction		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	19 / 7890 (0.24%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	0 / 19	2 / 15
deaths causally related to treatment / all	0 / 8	0 / 5
Haemorrhagic transformation stroke		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Headache		
subjects affected / exposed	7 / 7890 (0.09%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	1 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Hemianopia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegic migraine		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hypertensive encephalopathy</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoaesthesia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoglycaemic coma</b>		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoglycaemic unconsciousness</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypotonia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoxic-ischaemic encephalopathy</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intercostal neuralgia</b>		
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intracranial aneurysm</b>		

subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intraventricular haemorrhage</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic cerebral infarction</b>		
subjects affected / exposed	20 / 7890 (0.25%)	13 / 7912 (0.16%)
occurrences causally related to treatment / all	0 / 22	1 / 14
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Ischaemic neuropathy</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic stroke</b>		
subjects affected / exposed	97 / 7890 (1.23%)	94 / 7912 (1.19%)
occurrences causally related to treatment / all	1 / 107	1 / 99
deaths causally related to treatment / all	0 / 4	0 / 15
<b>Lacunar infarction</b>		
subjects affected / exposed	6 / 7890 (0.08%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lethargy</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Loss of consciousness</b>		
subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Memory impairment</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningoradiculitis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Migraine</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mononeuritis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Monoparesis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Movement disorder</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nerve compression</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nerve root compression</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nervous system disorder</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Neuralgia</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuritis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuritis cranial</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurological symptom</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuropathy peripheral</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Normal pressure hydrocephalus</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orthostatic intolerance</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paraesthesia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paraplegia</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paresis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parkinson's disease</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peripheral nerve paresis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polyneuropathy</b>		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polyneuropathy chronic</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post herpetic neuralgia</b>		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	16 / 7890 (0.20%)	16 / 7912 (0.20%)
occurrences causally related to treatment / all	0 / 16	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudoradicular syndrome		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular syndrome		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculitis lumbosacral		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Restless legs syndrome		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retrograde amnesia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reversible ischaemic neurological deficit		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ruptured cerebral aneurysm</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sciatica</b>		
subjects affected / exposed	6 / 7890 (0.08%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Senile dementia</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sensory disturbance</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sensory loss</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Simple partial seizures</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Somnolence</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Spinal claudication</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord disorder		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stupor		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	7 / 7890 (0.09%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Syncope		

subjects affected / exposed	79 / 7890 (1.00%)	72 / 7912 (0.91%)
occurrences causally related to treatment / all	0 / 81	0 / 77
deaths causally related to treatment / all	0 / 1	0 / 1
Thalamic infarction		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic cerebral infarction		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic stroke		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	87 / 7890 (1.10%)	67 / 7912 (0.85%)
occurrences causally related to treatment / all	4 / 98	0 / 75
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	0 / 7890 (0.00%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal neuralgia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
VIIth nerve paralysis		

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vlith nerve paralysis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular parkinsonism		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery stenosis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo CNS origin		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
White matter lesion		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery embolism		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery occlusion		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery stenosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral circulatory failure		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (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	2 / 7890 (0.03%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 2
Cerebral infarction		
subjects affected / exposed	7 / 7890 (0.09%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	0 / 7	1 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebral ischaemia		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	28 / 7890 (0.35%)	33 / 7912 (0.42%)
occurrences causally related to treatment / all	0 / 28	0 / 33
deaths causally related to treatment / all	0 / 3	0 / 10
Cerebrovascular disorder		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cervical myelopathy		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Complex partial seizures		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complex regional pain syndrome		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Convulsion		
subjects affected / exposed	8 / 7890 (0.10%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Critical illness polyneuropathy		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Dementia		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia with Lewy bodies		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed level of consciousness		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic hyperosmolar coma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	52 / 7890 (0.66%)	42 / 7912 (0.53%)	
occurrences causally related to treatment / all	2 / 54	0 / 43	
deaths causally related to treatment / all	1 / 3	0 / 1	
<b>Anaemia macrocytic</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaemia megaloblastic</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaemia of chronic disease</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bone marrow failure</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bone marrow ischaemia</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Coagulopathy</b>			

subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated intravascular coagulation		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 3
Febrile neutropenia		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Haemolytic anaemia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhagic anaemia		
subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Hyperprothrombinaemia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic thrombocytopenic purpura		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		

subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Jaundice acholuric		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spontaneous haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	7 / 7890 (0.09%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	1 / 7	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Ear and labyrinth disorders</b>			
<b>Deafness</b>			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Otosclerosis</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ototoxicity</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sudden hearing loss</b>			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tinnitus</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo</b>			
subjects affected / exposed	6 / 7890 (0.08%)	14 / 7912 (0.18%)	
occurrences causally related to treatment / all	0 / 6	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo labyrinthine</b>			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo positional</b>			

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	16 / 7890 (0.20%)	16 / 7912 (0.20%)	
occurrences causally related to treatment / all	0 / 20	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryostenosis acquired			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic eye disease			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eye disorder		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemorrhage		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye pain		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid ptosis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular retrobulbar haemorrhage		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular vascular disorder		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmoplegia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pterygium		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery thrombosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal degeneration		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal ischaemia		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal tear		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vascular thrombosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein occlusion		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulcerative keratitis		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	5 / 7890 (0.06%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	25 / 7890 (0.32%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	1 / 25	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	7 / 7890 (0.09%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	1 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal strangulated hernia		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall mass		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute abdomen		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anorectal disorder		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix disorder		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Buccal polyp		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	12 / 7890 (0.15%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	5 / 7890 (0.06%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Colitis ulcerative		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic stenosis		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	5 / 7890 (0.06%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dental caries		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic hernia		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	21 / 7890 (0.27%)	23 / 7912 (0.29%)
occurrences causally related to treatment / all	3 / 21	3 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea haemorrhagic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dieulafoy's vascular malformation		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	5 / 7890 (0.06%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal polyp		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 6	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		

subjects affected / exposed	7 / 7890 (0.09%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	2 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal vascular ectasia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Enteritis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epigastric discomfort		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive duodenitis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecal incontinence		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faeces discoloured		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia, obstructive		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Frequent bowel movements		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallstone ileus		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric dysplasia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	3 / 7890 (0.04%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric polyps		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	7 / 7890 (0.09%)	17 / 7912 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 17
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	1 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Gastritis		
subjects affected / exposed	18 / 7890 (0.23%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	2 / 18	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis atrophic		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		

subjects affected / exposed	7 / 7890 (0.09%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia haemorrhagic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal erosion		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	26 / 7890 (0.33%)	30 / 7912 (0.38%)
occurrences causally related to treatment / all	0 / 27	0 / 31
deaths causally related to treatment / all	0 / 2	0 / 2
Gastrointestinal ischaemia		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal motility disorder		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal pain		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	18 / 7890 (0.23%)	14 / 7912 (0.18%)
occurrences causally related to treatment / all	0 / 18	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophagitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		

subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	8 / 7890 (0.10%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia oral		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileal ulcer		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		

subjects affected / exposed	7 / 7890 (0.09%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	1 / 7	1 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
Ileus paralytic		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	48 / 7890 (0.61%)	31 / 7912 (0.39%)
occurrences causally related to treatment / all	0 / 50	0 / 33
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia, obstructive		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Internal hernia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal infarction		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal ischaemia		
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1
Intestinal obstruction		

subjects affected / exposed	7 / 7890 (0.09%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 3	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	16 / 7890 (0.20%)	21 / 7912 (0.27%)
occurrences causally related to treatment / all	0 / 16	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 0
Lip haematoma		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	10 / 7890 (0.13%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Lumbar hernia		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mallory-Weiss syndrome</b>		
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Melaena</b>		
subjects affected / exposed	3 / 7890 (0.04%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesenteric artery stenosis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesenteric occlusion</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesenteric panniculitis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mouth cyst</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nausea</b>		
subjects affected / exposed	12 / 7890 (0.15%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 13	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema mouth</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous pancreatitis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal dysplasia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal perforation		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer haemorrhage		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Oral pain		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic calcification		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic disorder		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	15 / 7890 (0.19%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	2 / 20	2 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	12 / 7890 (0.15%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	1 / 13	1 / 7
deaths causally related to treatment / all	0 / 2	0 / 0
Pancreatitis chronic		
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis haemorrhagic		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis necrotising		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Papilla of Vater stenosis		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia oral		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer perforation		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumatosis intestinalis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Poor dental condition		
subjects affected / exposed	0 / 7890 (0.00%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctalgia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis ulcerative		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	9 / 7890 (0.11%)	13 / 7912 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Retroperitoneal haemorrhage		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small intestinal obstruction		

subjects affected / exposed	9 / 7890 (0.11%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal perforation		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spigelian hernia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stomach mass		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Subileus		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Tooth disorder		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toothache		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	7 / 7890 (0.09%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia, obstructive		

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	16 / 7890 (0.20%)	18 / 7912 (0.23%)	
occurrences causally related to treatment / all	0 / 17	1 / 18	
deaths causally related to treatment / all	0 / 2	0 / 0	
Volvulus			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	12 / 7890 (0.15%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 14	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cold sweat			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			

subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Dermatitis allergic</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic foot</b>		
subjects affected / exposed	14 / 7890 (0.18%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 20	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Drug eruption</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ecchymosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Eczema</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Eczema asteatotic</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erythema multiforme</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erythema nodosum</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hyperhidrosis		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keloid scar		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytoclastic vasculitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigoid		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus		
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyoderma gangrenosum		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rash</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rash generalised</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin disorder</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin necrosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin ulcer</b>		
subjects affected / exposed	8 / 7890 (0.10%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stasis dermatitis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Swelling face</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urticaria</b>		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>Acute prerenal failure</b>			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Bladder dilatation</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder discomfort</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder dysfunction</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder hypertrophy</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Calculus bladder</b>			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Calculus ureteric</b>			
subjects affected / exposed	9 / 7890 (0.11%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Calculus urinary</b>			

subjects affected / exposed	5 / 7890 (0.06%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis glandularis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis ulcerative		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis chronic		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematuria</b>		
subjects affected / exposed	15 / 7890 (0.19%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	0 / 18	0 / 22
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hydronephrosis</b>		
subjects affected / exposed	7 / 7890 (0.09%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Incontinence</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower urinary tract symptoms</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Micturition disorder</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephritic syndrome</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrolithiasis</b>		
subjects affected / exposed	10 / 7890 (0.13%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrotic syndrome</b>		

subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Neurogenic bladder		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pollakiuria		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery arteriosclerosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery dissection		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst haemorrhage		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.22%)	31 / 7912 (0.39%)
occurrences causally related to treatment / all	0 / 17	1 / 34
deaths causally related to treatment / all	0 / 8	0 / 5
Renal failure acute		
subjects affected / exposed	61 / 7890 (0.77%)	83 / 7912 (1.05%)
occurrences causally related to treatment / all	2 / 79	0 / 91
deaths causally related to treatment / all	1 / 10	0 / 11
Renal failure chronic		
subjects affected / exposed	13 / 7890 (0.16%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	0 / 15	0 / 10
deaths causally related to treatment / all	0 / 5	0 / 0
Renal haemorrhage		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	8 / 7890 (0.10%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	1 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Renal infarct		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal pain		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal tubular necrosis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stress urinary incontinence</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tubulointerstitial nephritis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ureteric obstruction</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ureteric stenosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urethral disorder</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urethral stenosis</b>		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary bladder haemorrhage</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	19 / 7890 (0.24%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 20	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adrenal insufficiency			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cyst			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.01%)	0 / 7912 (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			
Arthralgia			
subjects affected / exposed	19 / 7890 (0.24%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 19	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arthritis			

subjects affected / exposed	7 / 7890 (0.09%)	13 / 7912 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis reactive		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropathy		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Articular calcification		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Back disorder		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	27 / 7890 (0.34%)	20 / 7912 (0.25%)
occurrences causally related to treatment / all	0 / 31	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Bone erosion		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone fistula		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone lesion		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bone pain		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	9 / 7890 (0.11%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondromalacia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondropathy		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fistula		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inclusion body myositis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal mass		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		

subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc disorder</b>		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc displacement</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc protrusion</b>		
subjects affected / exposed	24 / 7890 (0.30%)	16 / 7912 (0.20%)
occurrences causally related to treatment / all	0 / 25	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint effusion</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint swelling</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb discomfort</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar spinal stenosis</b>		
subjects affected / exposed	9 / 7890 (0.11%)	13 / 7912 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metatarsalgia</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Monarthritis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle spasms</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscular weakness</b>		
subjects affected / exposed	6 / 7890 (0.08%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal chest pain</b>		
subjects affected / exposed	9 / 7890 (0.11%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal discomfort</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal pain</b>		
subjects affected / exposed	6 / 7890 (0.08%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia</b>		

subjects affected / exposed	6 / 7890 (0.08%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 6	2 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myofascial pain syndrome</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myositis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neck pain</b>		
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteitis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Osteoarthritis</b>		
subjects affected / exposed	78 / 7890 (0.99%)	73 / 7912 (0.92%)
occurrences causally related to treatment / all	0 / 86	0 / 81
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteochondrosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteonecrosis</b>		
subjects affected / exposed	5 / 7890 (0.06%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoporosis</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain in extremity</b>		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pathological fracture</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periarthritis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polyarthritis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polymyalgia rheumatica</b>		
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rhabdomyolysis</b>		
subjects affected / exposed	4 / 7890 (0.05%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	1 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Rheumatoid arthritis</b>		

subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rotator cuff syndrome</b>		
subjects affected / exposed	9 / 7890 (0.11%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scoliosis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal column stenosis</b>		
subjects affected / exposed	16 / 7890 (0.20%)	13 / 7912 (0.16%)
occurrences causally related to treatment / all	0 / 16	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal deformity</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal osteoarthritis</b>		
subjects affected / exposed	12 / 7890 (0.15%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 13	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylitis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylolisthesis</b>		
subjects affected / exposed	3 / 7890 (0.04%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylolysis</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Synovitis</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tendon disorder</b>			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tendonitis</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tenosynovitis</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tenosynovitis stenosans</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertebral foraminal stenosis</b>			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal sepsis</b>			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal wall abscess</b>		
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal wall infection</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess</b>		
subjects affected / exposed	5 / 7890 (0.06%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess jaw</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess limb</b>		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Acute hepatitis B</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Acute pulmonary histoplasmosis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Amoebiasis</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anal abscess</b>		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendiceal abscess</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendicitis</b>		
subjects affected / exposed	19 / 7890 (0.24%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	0 / 19	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendicitis perforated</b>		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arteriosclerotic gangrene</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Arthritis bacterial</b>		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthritis infective</b>		
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteraemia</b>		

subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial pyelonephritis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial sepsis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Biliary sepsis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone abscess</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Borrelia infection</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		
subjects affected / exposed	18 / 7890 (0.23%)	24 / 7912 (0.30%)
occurrences causally related to treatment / all	0 / 18	0 / 27
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Bronchopneumonia</b>		
subjects affected / exposed	7 / 7890 (0.09%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 4
<b>Bursitis infective</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carbuncle		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site infection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	46 / 7890 (0.58%)	38 / 7912 (0.48%)
occurrences causally related to treatment / all	0 / 53	0 / 44
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis gangrenous		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis suppurative		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cholecystitis infective		

subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic sinusitis		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Device related sepsis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated tuberculosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Diverticulitis		
subjects affected / exposed	11 / 7890 (0.14%)	15 / 7912 (0.19%)
occurrences causally related to treatment / all	0 / 11	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 1
Dysentery		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ear infection		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Echinococcosis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Empyema		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis enterococcal		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endocarditis staphylococcal		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometritis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endophthalmitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter infection		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal infection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Enterococcal sepsis		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Enterocolitis infectious		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottitis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	14 / 7890 (0.18%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 14	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia infection		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia sepsis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia urinary tract infection</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>External ear cellulitis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Extradural abscess</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Febrile infection</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fungal oesophagitis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gallbladder empyema</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gangrene</b>		

subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis viral		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	29 / 7890 (0.37%)	31 / 7912 (0.39%)
occurrences causally related to treatment / all	0 / 32	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis rotavirus		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal viral infection		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Genital infection fungal		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Giardiasis		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Graft infection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
H1N1 influenza		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HIV infection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haematoma infection		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter infection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis E		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis viral		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster ophthalmic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Histoplasmosis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bites		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infective myositis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	7 / 7890 (0.09%)	7 / 7912 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0
Intertrigo candida		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keratitis herpetic		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leptospirosis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lobar pneumonia		
subjects affected / exposed	17 / 7890 (0.22%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 17	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Localised infection		
subjects affected / exposed	9 / 7890 (0.11%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Lower respiratory tract infection		
subjects affected / exposed	10 / 7890 (0.13%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	8 / 7890 (0.10%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Lyme disease		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphangitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mediastinitis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningitis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningitis bacterial</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Meningitis cryptococcal</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Mycoplasma infection</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mycotoxycosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nasopharyngitis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Necrotising fasciitis</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Oesophageal candidiasis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orchitis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis</b>		
subjects affected / exposed	7 / 7890 (0.09%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis chronic</b>		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 chronic</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paronychia</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal abscess		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital cellulitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal abscess		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	7 / 7890 (0.09%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Peritonsillar abscess		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmodium vivax infection		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal sepsis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	160 / 7890 (2.03%)	139 / 7912 (1.76%)
occurrences causally related to treatment / all	0 / 176	0 / 157
deaths causally related to treatment / all	0 / 20	0 / 18
Pneumonia bacterial		
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Pneumonia chlamydial		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Pneumonia klebsiella		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia necrotising		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	3 / 7890 (0.04%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic abscess		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal bacteraemia		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonas infection		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoas abscess		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Pyelonephritis		
subjects affected / exposed	6 / 7890 (0.08%)	12 / 7912 (0.15%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyopneumothorax		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory tract infection		

subjects affected / exposed	7 / 7890 (0.09%)	8 / 7912 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory tract infection viral		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal abscess		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal infection		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonella sepsis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal abscess		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrub typhus		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		

subjects affected / exposed	23 / 7890 (0.29%)	35 / 7912 (0.44%)
occurrences causally related to treatment / all	0 / 25	0 / 37
deaths causally related to treatment / all	0 / 8	0 / 15
<b>Sepsis syndrome</b>		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Septic embolus</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Septic shock</b>		
subjects affected / exposed	25 / 7890 (0.32%)	9 / 7912 (0.11%)
occurrences causally related to treatment / all	0 / 26	1 / 10
deaths causally related to treatment / all	0 / 17	0 / 3
<b>Sialoadenitis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinobronchitis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinusitis</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin infection</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Soft tissue infection</b>		

subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	6 / 7890 (0.08%)	6 / 7912 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal osteomyelitis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal infection		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Streptococcal sepsis		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subacute endocarditis		

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superinfection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected transmission of an infectious agent via product			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinea pedis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis viral		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	3 / 7890 (0.04%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Urethritis		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	36 / 7890 (0.46%)	43 / 7912 (0.54%)
occurrences causally related to treatment / all	0 / 49	0 / 44
deaths causally related to treatment / all	0 / 1	0 / 2
Urinary tract infection bacterial		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Urinary tract infection pseudomonal		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urosepsis</b>		
subjects affected / exposed	15 / 7890 (0.19%)	14 / 7912 (0.18%)
occurrences causally related to treatment / all	0 / 20	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 3
<b>Vaginal abscess</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Varicella</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Wound sepsis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Alcohol poisoning</b>		
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular pseudoaneurysm</b>		
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis bacterial</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vestibular neuronitis</b>		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Viral tracheitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	6 / 7890 (0.08%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cachexia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Decreased appetite			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	24 / 7890 (0.30%)	33 / 7912 (0.42%)
occurrences causally related to treatment / all	0 / 27	0 / 33
deaths causally related to treatment / all	0 / 1	0 / 1
Diabetes mellitus		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	8 / 7890 (0.10%)	26 / 7912 (0.33%)
occurrences causally related to treatment / all	0 / 9	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic complication		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Failure to thrive		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Fluid overload		

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fructose intolerance		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	9 / 7890 (0.11%)	11 / 7912 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 1
Hyperlipidaemia		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar state		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoalbuminaemia		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	26 / 7890 (0.33%)	24 / 7912 (0.30%)
occurrences causally related to treatment / all	0 / 28	0 / 26
deaths causally related to treatment / all	0 / 1	0 / 0
Hypokalaemia		
subjects affected / exposed	7 / 7890 (0.09%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	8 / 7890 (0.10%)	10 / 7912 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0
Hypophosphataemia		

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypovolaemia</b>		
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Insulin-requiring type 2 diabetes mellitus</b>		
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ketoacidosis</b>		
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malnutrition</b>		
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Metabolic acidosis</b>		
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Metabolic syndrome</b>		
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	4 / 7912 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Type 1 diabetes mellitus</b>		

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	37 / 7890 (0.47%)	27 / 7912 (0.34%)	
occurrences causally related to treatment / all	0 / 38	0 / 28	
deaths causally related to treatment / all	0 / 1	0 / 1	
Vitamin B12 deficiency			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin D deficiency			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

<b>Non-serious adverse events</b>	Placebo	Darapladib	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4885 / 7890 (61.91%)	5171 / 7912 (65.36%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	660 / 7890 (8.37%)	643 / 7912 (8.13%)	
occurrences (all)	751	749	
Hypotension			
subjects affected / exposed	181 / 7890 (2.29%)	184 / 7912 (2.33%)	
occurrences (all)	198	201	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	357 / 7890 (4.52%)	354 / 7912 (4.47%)	
occurrences (all)	384	377	
Non-cardiac chest pain			

subjects affected / exposed occurrences (all)	376 / 7890 (4.77%) 458	366 / 7912 (4.63%) 425	
Oedema peripheral subjects affected / exposed occurrences (all)	419 / 7890 (5.31%) 468	431 / 7912 (5.45%) 497	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	404 / 7890 (5.12%) 471	401 / 7912 (5.07%) 464	
Dyspnoea subjects affected / exposed occurrences (all)	346 / 7890 (4.39%) 395	324 / 7912 (4.10%) 354	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	164 / 7890 (2.08%) 170	126 / 7912 (1.59%) 135	
Investigations			
Blood glucose increased subjects affected / exposed occurrences (all)	181 / 7890 (2.29%) 208	171 / 7912 (2.16%) 183	
Blood pressure increased subjects affected / exposed occurrences (all)	197 / 7890 (2.50%) 236	173 / 7912 (2.19%) 193	
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	528 / 7890 (6.69%) 645	457 / 7912 (5.78%) 563	
Atrial fibrillation subjects affected / exposed occurrences (all)	245 / 7890 (3.11%) 274	257 / 7912 (3.25%) 292	
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	357 / 7890 (4.52%) 410	296 / 7912 (3.74%) 340	
Dizziness			

subjects affected / exposed occurrences (all)	491 / 7890 (6.22%) 556	456 / 7912 (5.76%) 533	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	208 / 7890 (2.64%) 220	191 / 7912 (2.41%) 204	
Eye disorders Cataract subjects affected / exposed occurrences (all)	198 / 7890 (2.51%) 254	203 / 7912 (2.57%) 259	
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	188 / 7890 (2.38%) 213	163 / 7912 (2.06%) 183	
Abdominal pain upper subjects affected / exposed occurrences (all)	152 / 7890 (1.93%) 167	180 / 7912 (2.28%) 194	
Abnormal faeces subjects affected / exposed occurrences (all)	63 / 7890 (0.80%) 66	728 / 7912 (9.20%) 762	
Constipation subjects affected / exposed occurrences (all)	255 / 7890 (3.23%) 271	247 / 7912 (3.12%) 260	
Diarrhoea subjects affected / exposed occurrences (all)	479 / 7890 (6.07%) 566	949 / 7912 (11.99%) 1185	
Dyspepsia subjects affected / exposed occurrences (all)	182 / 7890 (2.31%) 197	177 / 7912 (2.24%) 197	
Flatulence subjects affected / exposed occurrences (all)	92 / 7890 (1.17%) 96	189 / 7912 (2.39%) 211	
Gastritis subjects affected / exposed occurrences (all)	192 / 7890 (2.43%) 204	159 / 7912 (2.01%) 166	
Gastrooesophageal reflux disease			

subjects affected / exposed occurrences (all)	160 / 7890 (2.03%) 169	144 / 7912 (1.82%) 160	
Large intestine polyp subjects affected / exposed occurrences (all)	265 / 7890 (3.36%) 328	259 / 7912 (3.27%) 285	
Nausea subjects affected / exposed occurrences (all)	222 / 7890 (2.81%) 250	228 / 7912 (2.88%) 253	
Skin and subcutaneous tissue disorders Skin odour abnormal subjects affected / exposed occurrences (all)	34 / 7890 (0.43%) 38	383 / 7912 (4.84%) 425	
Renal and urinary disorders Urine odour abnormal subjects affected / exposed occurrences (all)	81 / 7890 (1.03%) 83	473 / 7912 (5.98%) 491	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	401 / 7890 (5.08%) 468	385 / 7912 (4.87%) 449	
Back pain subjects affected / exposed occurrences (all)	466 / 7890 (5.91%) 514	421 / 7912 (5.32%) 457	
Muscle spasms subjects affected / exposed occurrences (all)	168 / 7890 (2.13%) 184	164 / 7912 (2.07%) 185	
Musculoskeletal pain subjects affected / exposed occurrences (all)	219 / 7890 (2.78%) 239	180 / 7912 (2.28%) 190	
Myalgia subjects affected / exposed occurrences (all)	244 / 7890 (3.09%) 290	207 / 7912 (2.62%) 221	
Osteoarthritis subjects affected / exposed occurrences (all)	176 / 7890 (2.23%) 198	167 / 7912 (2.11%) 183	
Pain in extremity			

subjects affected / exposed occurrences (all)	354 / 7890 (4.49%) 399	315 / 7912 (3.98%) 357	
<b>Infections and infestations</b>			
Bronchitis			
subjects affected / exposed	416 / 7890 (5.27%)	389 / 7912 (4.92%)	
occurrences (all)	523	489	
Influenza			
subjects affected / exposed	253 / 7890 (3.21%)	223 / 7912 (2.82%)	
occurrences (all)	305	263	
Nasopharyngitis			
subjects affected / exposed	588 / 7890 (7.45%)	548 / 7912 (6.93%)	
occurrences (all)	754	825	
Sinusitis			
subjects affected / exposed	189 / 7890 (2.40%)	157 / 7912 (1.98%)	
occurrences (all)	231	195	
Upper respiratory tract infection			
subjects affected / exposed	425 / 7890 (5.39%)	367 / 7912 (4.64%)	
occurrences (all)	534	492	
Urinary tract infection			
subjects affected / exposed	296 / 7890 (3.75%)	260 / 7912 (3.29%)	
occurrences (all)	375	331	
<b>Metabolism and nutrition disorders</b>			
Type 2 diabetes mellitus			
subjects affected / exposed	608 / 7890 (7.71%)	566 / 7912 (7.15%)	
occurrences (all)	633	592	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 August 2009	Clarification and correction of different items in protocol. RATIONALE: Following initial investigator meetings and discussions of the original protocol, it became apparent that changes were needed to improve understanding of the protocol.
11 February 2010	The primary intent of this amendment was to add a single cognitive function assessment (Montreal Cognitive Assessment) for all participants (if an approved translation was available) prior to the end of the study. RATIONALE: This change added an exploratory assessment that was of scientific interest and may be relevant to planning future clinical trials among this patient population.
29 July 2010	The primary intent of this amendment was to revise the threshold for excluding participants of Japanese, Chinese, or Korean ancestry with plasma levels of Lp-PLA2 activity from $\leq 10$ to $\leq 20.0$ nanomoles (nmol)/minute (min)/milliliter (mL). RATIONALE: The original text excluded Japanese, Chinese, and Korean participants with plasma Lp-PLA2 activity $\leq 10$ nmol/min/mL prior to randomization. This threshold was intended to be a surrogate measure for being homozygous for the 279F null variant allele, predominantly found in East Asians, and was listed as an exclusion criterion to avoid randomizing participants who would not be expected to produce circulating levels of the Lp-PLA2 enzyme. As participants who were homozygous for the 279F null allele would have no Lp-PLA2 enzyme to inhibit, it was important to identify these participants since there would be no clear rationale for exposing such participants to the investigational Lp-PLA2 inhibitor darapladib. Data from participants with chronic coronary heart disease in this study determined that Japanese, Chinese, and Korean participants who were homozygous for the 279F variant had reported baseline plasma Lp-PLA2 activity levels approaching 20.0 nmol/min/mL when measured by the assay used in this study. The text for the exclusion criterion pertaining to Japanese, Chinese, and Korean participants revised the threshold for the plasma Lp-PLA2 activity to $\leq 20.0$ nmol/min/mL prior to randomization, which was expected to help ensure that Japanese, Chinese, and Korean participants who were homozygous for the 279F variant were not enrolled.
29 March 2012	The primary intent of this amendment was to allow the Follow-up visit to be conducted by telephone in participants who met pre-defined criteria. RATIONALE: This change allowed collection of study endpoints/safety data in participants unable to attend a Follow-up clinic visit.
10 October 2012	The primary intent was to allow increased collection of data on new cancer, recurrence of cancer, or progression of cancer; and adjudication of all GI neoplasms (malignant and benign) and all GI polyps (malignant, and benign, and non-neoplastic). RATIONALE: Darapladib was given by oral gavage to male and female rodents starting from before sexual maturation and continuing every day throughout their lifetime for up to 2 years. Data from these studies became available prior to the end of the study. Overall, the data suggested drug-related increases in the incidence of adenomas and/or adenocarcinomas of the jejunum in male mice and male rats given higher doses of darapladib. The Independent Data Monitoring Committee for both this study and the other Phase III study (Study SB480848/033) reviewed these data and re-reviewed the safety data, including reports of tumors in study participants. Following this review, the IDMC recommended that the trials continue without any changes. However, this protocol change was proposed and incorporated by the sponsor to allow a more thorough review of neoplasms reported in this study.

29 November 2012	This country-specific amendment for France was required by the French regulatory authority (ANSM). Participants diagnosed with inflammatory bowel disease (Crohn's disease or ulcerative colitis) must immediately discontinue investigational product (IP).
------------------	--

Notes:

---

### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported