



Clinical trial results:

A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function Summary

EudraCT number	2017-002644-32
Trial protocol	CZ LV GB HU SE NO FR NL DK ES LT EE PT BE GR BG IT RO
Global end of trial date	08 July 2020

Results information

Result version number	v1 (current)
This version publication date	17 July 2021
First version publication date	17 July 2021

Trial information

Trial identification

Sponsor protocol code	EFC14875
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03315143
WHO universal trial number (UTN)	U1111-1187-8703

Notes:

Sponsors

Sponsor organisation name	Lexicon Pharmaceuticals, Inc.
Sponsor organisation address	8800 Technology Forest Place, The Woodlands, United States, TX 77381
Public contact	Medical Affairs, Lexicon Pharmaceuticals, Inc., medical-information@lexpharma.com
Scientific contact	Medical Affairs, Lexicon Pharmaceuticals, Inc., medical-information@lexpharma.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 July 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 July 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to compare the effect of sotagliflozin to placebo on total occurrences of cardiovascular (CV) death, hospitalization for heart failure [HHF], and urgent visit for heart failure [HF] in patients with type 2 diabetes, cardiovascular risk factors, and moderate to severely impaired renal function.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 December 2017
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	Netherlands: 46
Country: Number of subjects enrolled	Norway: 30
Country: Number of subjects enrolled	Poland: 443
Country: Number of subjects enrolled	Portugal: 200
Country: Number of subjects enrolled	Slovakia: 206
Country: Number of subjects enrolled	Spain: 352
Country: Number of subjects enrolled	Sweden: 86
Country: Number of subjects enrolled	United Kingdom: 93
Country: Number of subjects enrolled	Belgium: 88
Country: Number of subjects enrolled	Bulgaria: 246
Country: Number of subjects enrolled	Czechia: 170
Country: Number of subjects enrolled	Denmark: 88
Country: Number of subjects enrolled	Estonia: 45
Country: Number of subjects enrolled	France: 90
Country: Number of subjects enrolled	Germany: 103
Country: Number of subjects enrolled	Greece: 49
Country: Number of subjects enrolled	Hungary: 223
Country: Number of subjects enrolled	Italy: 176
Country: Number of subjects enrolled	Latvia: 83

Country: Number of subjects enrolled	Lithuania: 95
Country: Number of subjects enrolled	Canada: 330
Country: Number of subjects enrolled	United States: 1166
Country: Number of subjects enrolled	Argentina: 772
Country: Number of subjects enrolled	Brazil: 838
Country: Number of subjects enrolled	Chile: 471
Country: Number of subjects enrolled	Guatemala: 136
Country: Number of subjects enrolled	Mexico: 647
Country: Number of subjects enrolled	Peru: 305
Country: Number of subjects enrolled	Australia: 167
Country: Number of subjects enrolled	China: 119
Country: Number of subjects enrolled	India: 286
Country: Number of subjects enrolled	Israel: 106
Country: Number of subjects enrolled	Korea, Republic of: 68
Country: Number of subjects enrolled	New Zealand: 181
Country: Number of subjects enrolled	South Africa: 242
Country: Number of subjects enrolled	Taiwan: 104
Country: Number of subjects enrolled	Switzerland: 19
Country: Number of subjects enrolled	Georgia: 184
Country: Number of subjects enrolled	North Macedonia: 52
Country: Number of subjects enrolled	Romania: 241
Country: Number of subjects enrolled	Russian Federation: 499
Country: Number of subjects enrolled	Serbia: 112
Country: Number of subjects enrolled	Turkey: 300
Country: Number of subjects enrolled	Ukraine: 327
Worldwide total number of subjects	10584
EEA total number of subjects	3060

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)	3224
From 65 to 84 years	7197
85 years and over	163

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study at 723 study centers in North America, Latin America, Western Europe, Eastern Europe, and the Rest of the World from 19 Dec 2017 to 08 July 2020.

Pre-assignment

Screening details:

Subjects with a diagnosis of Type 2 diabetes (T2D), CV risk factors, and moderately impaired renal function were enrolled equally in 1 of 2 treatment groups, sotagliflozin or placebo.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Sotagliflozin

Arm description:

Sotagliflozin 200 mg tablet once daily, with possible up-titration in the first 6 months to 400 mg, for up to 28.9 months.

Arm type	Experimental
Investigational medicinal product name	Sotagliflozin
Investigational medicinal product code	SAR439954
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Sotagliflozin was administered as a tablet(s), orally once daily.

Arm title	Placebo
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Arm description:

Matching placebo to sotagliflozin 200 mg once daily, with possible up-titration in the first 6 months to matching placebo to sotagliflozin 400 mg, for up to 29.6 months.

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

Dosage and administration details:

Placebo was administered as a tablet(s) (identical to the sotagliflozin tablet in appearance), orally once daily.

Number of subjects in period 1	Sotagliflozin	Placebo
Started	5292	5292
Randomised and treated	5291	5286
Completed	0	0
Not completed	5292	5292
Death	240	246
Site terminated by sponsor	256	282
Study terminated by sponsor	4723	4664
Reason not specified	16	32
Withdrawal by subject	57	68

Baseline characteristics

Reporting groups

Reporting group title	Sotagliflozin
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Reporting group description:

Sotagliflozin 200 mg tablet once daily, with possible up-titration in the first 6 months to 400 mg, for up to 28.9 months.

Reporting group title	Placebo
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Reporting group description:

Matching placebo to sotagliflozin 200 mg once daily, with possible up-titration in the first 6 months to matching placebo to sotagliflozin 400 mg, for up to 29.6 months.

Reporting group values	Sotagliflozin	Placebo	Total
Number of subjects	5292	5292	10584
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	68.4 ± 8.4	68.2 ± 8.4	-
Gender categorical Units: Subjects			
Female	2347	2407	4754
Male	2945	2885	5830
Race Units: Subjects			
White	4383	4329	8712
Black or African American	176	187	363
Asian	317	365	682
American Indian or Alaska Native	205	216	421
Native Hawaiian or other Pacific Islander	25	15	40
Multiple	129	114	243
Not Reported	29	27	56
Unknown	25	32	57
Missing	3	7	10
Ethnicity Units: Subjects			
Hispanic or Latino	1671	1678	3349
Not Hispanic or Latino	3593	3581	7174
Not Reported	16	22	38
Unknown	11	11	22
Missing	1	0	1

End points

End points reporting groups

Reporting group title	Sotagliflozin
Reporting group description: Sotagliflozin 200 mg tablet once daily, with possible up-titration in the first 6 months to 400 mg, for up to 28.9 months.	
Reporting group title	Placebo
Reporting group description: Matching placebo to sotagliflozin 200 mg once daily, with possible up-titration in the first 6 months to matching placebo to sotagliflozin 400 mg, for up to 29.6 months.	

Primary: Number of Total Occurrences of Cardiovascular (CV) Death, Hospitalizations for Heart Failure (HHF) and Urgent Visits for Heart Failure (HF)

End point title	Number of Total Occurrences of Cardiovascular (CV) Death, Hospitalizations for Heart Failure (HHF) and Urgent Visits for Heart Failure (HF)
End point description: Combined endpoint of the total number of occurrences (first and potentially subsequent) of CV death, HHF, and urgent HF visits after randomisation. Events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. Intent-to-treat (ITT) population included all randomised subjects analysed according to the treatment group.	
End point type	Primary
End point timeframe: Up to 30 months	

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	5.6	7.5		

Statistical analyses

Statistical analysis title	Sotagliflozin vs Placebo
Statistical analysis description: The estimates of the hazard ratio (HR) and corresponding 2-sided 95% confidence interval (CI) was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-cardiovascular (non-CV) death treated as a competing event.	
Comparison groups	Placebo v Sotagliflozin

Number of subjects included in analysis	10584
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.88

Secondary: Total Number of Occurrences of HHF and Urgent HF Visits

End point title	Total Number of Occurrences of HHF and Urgent HF Visits
End point description:	
<p>Combined endpoint of the total occurrences (first and potentially subsequent) of HHF and urgent HF visits after randomisation. Events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. ITT population included all randomised subjects analysed according to the treatment group.</p>	
End point type	Secondary
End point timeframe:	
Up to 30 months	

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	3.5	5.1		

Statistical analyses

Statistical analysis title	Sotagliflozin vs Placebo
Statistical analysis description:	
<p>The estimates of the HR and corresponding 2-sided 95% CI was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-CV death treated as a competing event.</p>	
Comparison groups	Sotagliflozin v Placebo
Number of subjects included in analysis	10584
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.67

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.82

Secondary: Number of Deaths from Cardiovascular Causes

End point title	Number of Deaths from Cardiovascular Causes
End point description: Number of events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. ITT population included all randomised subjects analysed according to the treatment group.	
End point type	Secondary
End point timeframe: Up to 30 months	

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	2.2	2.4		

Statistical analyses

Statistical analysis title	Sotagliflozin vs Placebo
Statistical analysis description: The estimates of the HR and corresponding 2-sided 95% CI was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-CV death treated as a competing event.	
Comparison groups	Sotagliflozin v Placebo
Number of subjects included in analysis	10584
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.35
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.12

Secondary: Total Number of Occurrences of CV Death, HHF, Non-fatal Myocardial Infarction and Non-fatal Stroke

End point title	Total Number of Occurrences of CV Death, HHF, Non-fatal Myocardial Infarction and Non-fatal Stroke
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End point description:

Combined endpoint of the total number of occurrences (first and potentially subsequent) of CV death, HHF, non-fatal stroke, and non-fatal myocardial infarction after randomisation. Events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. ITT population included all randomised subjects analysed according to the treatment group.

End point type	Secondary
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End point timeframe:

Up to 30 months

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	7.6	10.4		

Statistical analyses

Statistical analysis title	Sotagliflozin vs Placebo
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Statistical analysis description:

The estimates of the HR and corresponding 2-sided 95% CI was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-CV death treated as a competing event.

Comparison groups	Sotagliflozin v Placebo
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Number of subjects included in analysis	10584
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Analysis specification	Pre-specified
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Analysis type	superiority
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Parameter estimate	Hazard ratio (HR)
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Point estimate	0.72
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	0.63
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upper limit	0.83
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Secondary: Total Number of Occurrences of HHF, Urgent HF Visit, CV Death, and HF While Hospitalized

End point title	Total Number of Occurrences of HHF, Urgent HF Visit, CV Death, and HF While Hospitalized
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End point description:

Combined endpoint of the total number of occurrences (first and potentially subsequent) after randomisation of HHF, urgent HF visits, CV Death and HF while hospitalised. Events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. ITT population included all randomised subjects analysed according to the treatment group.

End point type Secondary

End point timeframe:

Up to 30 months

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	6.4	8.3		

Statistical analyses

Statistical analysis title Sotagliflozin vs Placebo

Statistical analysis description:

The estimates of the HR and corresponding 2-sided 95% CI was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-CV death treated as a competing event.

Comparison groups	Placebo v Sotagliflozin
Number of subjects included in analysis	10584
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.89

Secondary: Number of Occurrences After Randomisation of the Composite of Sustained $\geq 50\%$ Decrease in Estimated Glomerular Filtration Rate (eGFR) from Baseline (for ≥ 30 days), Chronic Dialysis, Renal Transplant, or Sustained eGFR < 15 mL/min/1.73 m² (for ≥ 30 days)

End point title Number of Occurrences After Randomisation of the Composite of Sustained $\geq 50\%$ Decrease in Estimated Glomerular Filtration Rate (eGFR) from Baseline (for ≥ 30 days), Chronic Dialysis, Renal Transplant, or Sustained eGFR < 15 mL/min/1.73 m² (for ≥ 30 days)

End point description:

Events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. ITT population included all randomised subjects analysed according to the treatment group.

End point type	Secondary
End point timeframe:	
Up to 30 months	

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	0.5	0.7		

Statistical analyses

Statistical analysis title	Sotagliflozin vs Placebo
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Statistical analysis description:

The estimates of the HR and corresponding 2-sided 95% CI was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-CV death treated as a competing event.

Comparison groups	Placebo v Sotagliflozin
Number of subjects included in analysis	10584
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.08

Secondary: Number of Deaths from Any Cause

End point title	Number of Deaths from Any Cause
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End point description:

Number of events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. ITT population included all randomised subjects analysed according to the treatment group.

End point type	Secondary
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End point timeframe:

Up to 30 months

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	3.5	3.5		

Statistical analyses

Statistical analysis title	Sotagliflozin vs Placebo
Statistical analysis description:	
The estimates of the HR and corresponding 2-sided 95% CI was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-CV death treated as a competing event.	
Comparison groups	Sotagliflozin v Placebo
Number of subjects included in analysis	10584
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.18

Secondary: Total Number of Occurrences of CV Death, Non-fatal Myocardial Infarction and Non-fatal Stroke

End point title	Total Number of Occurrences of CV Death, Non-fatal Myocardial Infarction and Non-fatal Stroke
End point description:	
Combined endpoint of the total number of occurrences (first and potentially subsequent) of CV death and urgent HF visits after randomisation. Events that occurred during the study were calculated as the total number of events per 100 person-years of follow-up. ITT population included all randomised subjects analysed according to the treatment group.	
End point type	Secondary
End point timeframe:	
Up to 30 months	

End point values	Sotagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5292	5292		
Units: events per 100-person years				
number (not applicable)	4.8	6.3		

Statistical analyses

Statistical analysis title	Sotagliflozin vs Placebo
Statistical analysis description: The estimates of the HR and corresponding 2-sided 95% CI was to be provided by a marginal Cox proportional hazard model stratified by region and ejection fraction, with non-CV death treated as a competing event.	
Comparison groups	Sotagliflozin v Placebo
Number of subjects included in analysis	10584
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.91

Adverse events

Adverse events information

Timeframe for reporting adverse events:

First dose of study drug up to 10 days after the last dose of study drug (Up to 30 months)

Adverse event reporting additional description:

Number of Deaths (All causes) is based on all randomised subjects (n=5292, 5292). Adverse Events are based on the Safety population that included all randomised subjects who received at least 1 dose of investigational medicinal product (n=5291, 5286).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Sotagliflozin
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Reporting group description:

Sotagliflozin 200 mg tablet once daily, with possible up-titration in the first 6 months to 400 mg, for up to 28.9 months.

Reporting group title	Placebo
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Reporting group description:

Matching placebo to sotagliflozin 200 mg once daily, with possible up-titration in the first 6 months to matching placebo to sotagliflozin 400 mg, for up to 29.6 months.

Serious adverse events	Sotagliflozin	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1236 / 5291 (23.36%)	1331 / 5286 (25.18%)	
number of deaths (all causes)	246	246	
number of deaths resulting from adverse events	173	192	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
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 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma gastric			

subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Adenocarcinoma of colon		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Benign laryngeal neoplasm		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of urethra		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign renal neoplasm		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		

subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder cancer recurrent			
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma stage 0			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer			
subjects affected / exposed	3 / 5291 (0.06%)	5 / 5286 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Breast cancer stage III			

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burkitt's lymphoma stage IV		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cancer pain		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chloroma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	0 / 5291 (0.00%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 4
Chronic lymphocytic leukaemia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	6 / 5291 (0.11%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 1
Colon cancer stage 0		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer metastatic		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ear neoplasm		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
External ear neoplasm malignant		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Glioma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hodgkin's disease		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Keratoacanthoma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo maligna		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liposarcoma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm malignant		

subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Lung squamous cell carcinoma stage III		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma in situ		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant pleural effusion		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to lung		

subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to peritoneum		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic renal cell carcinoma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic uterine cancer		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Nasopharyngeal neoplasm benign		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour of the lung metastatic		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal carcinoma		

subjects affected / exposed	4 / 5291 (0.08%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Oropharyngeal cancer stage II		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	4 / 5291 (0.08%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 4
Pancreatic carcinoma metastatic		
subjects affected / exposed	5 / 5291 (0.09%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 0
Pancreatic neoplasm		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Papillary serous endometrial carcinoma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		

subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	10 / 5291 (0.19%)	13 / 5286 (0.25%)
occurrences causally related to treatment / all	0 / 11	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage IV		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer stage IV		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		

subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cancer		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seborrhoeic keratosis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testis cancer		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	2 / 5291 (0.04%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial haemorrhage			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			

subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Deep vein thrombosis		
subjects affected / exposed	6 / 5291 (0.11%)	15 / 5286 (0.28%)
occurrences causally related to treatment / all	0 / 7	3 / 16
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic vascular disorder		
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	6 / 5291 (0.11%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	1 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Essential hypertension		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery aneurysm		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	8 / 5291 (0.15%)	13 / 5286 (0.25%)
occurrences causally related to treatment / all	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		

subjects affected / exposed	7 / 5291 (0.13%)	13 / 5286 (0.25%)
occurrences causally related to treatment / all	0 / 7	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	4 / 5291 (0.08%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive urgency		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	5 / 5291 (0.09%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 5	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	3 / 5291 (0.06%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Internal haemorrhage		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	1 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic venous thrombosis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	16 / 5291 (0.30%)	15 / 5286 (0.28%)
occurrences causally related to treatment / all	0 / 19	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	1 / 5291 (0.02%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	5 / 5291 (0.09%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral embolism		

subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	8 / 5291 (0.15%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	2 / 8	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	0 / 5291 (0.00%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Subclavian steal syndrome		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vasculitis		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Aortic aneurysm repair			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve replacement			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker replacement			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary angioplasty			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot amputation			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterectomy			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular lens implant			

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve replacement			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Percutaneous coronary intervention			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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			
Asthenia			
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Chest pain			

subjects affected / exposed	7 / 5291 (0.13%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic fatigue syndrome			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	9 / 5291 (0.17%)	12 / 5286 (0.23%)	
occurrences causally related to treatment / all	1 / 9	0 / 12	
deaths causally related to treatment / all	1 / 9	0 / 12	
Fatigue			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza like illness			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site discharge			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site haematoma			

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Necrobiosis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	10 / 5291 (0.19%)	12 / 5286 (0.23%)
occurrences causally related to treatment / all	0 / 12	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	5 / 5291 (0.09%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Soft tissue inflammation		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		

subjects affected / exposed	14 / 5291 (0.26%)	8 / 5286 (0.15%)	
occurrences causally related to treatment / all	0 / 14	0 / 8	
deaths causally related to treatment / all	0 / 14	0 / 8	
Sudden death			
subjects affected / exposed	7 / 5291 (0.13%)	5 / 5286 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 7	0 / 5	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexa uteri cyst			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Benign prostatic hyperplasia			
subjects affected / exposed	7 / 5291 (0.13%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast pain			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular torsion			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval disorder			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	9 / 5291 (0.17%)	3 / 5286 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute respiratory failure			
subjects affected / exposed	11 / 5291 (0.21%)	12 / 5286 (0.23%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 2	
Aspiration			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			

subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial hyperreactivity		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	9 / 5291 (0.17%)	19 / 5286 (0.36%)
occurrences causally related to treatment / all	0 / 9	0 / 22
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic respiratory disease		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic respiratory failure		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		

subjects affected / exposed	9 / 5291 (0.17%)	10 / 5286 (0.19%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 0
Dyspnoea exertional		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	0 / 5291 (0.00%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nocturnal dyspnoea		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pickwickian syndrome		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	1 / 5291 (0.02%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		

subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pneumonitis			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	7 / 5291 (0.13%)	13 / 5286 (0.25%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 3	
Pulmonary fibrosis			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			

subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 5291 (0.00%)	8 / 5286 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory depression			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	8 / 5291 (0.15%)	8 / 5286 (0.15%)	
occurrences causally related to treatment / all	0 / 8	1 / 8	
deaths causally related to treatment / all	0 / 2	0 / 2	
Sleep apnoea syndrome			
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	4 / 5291 (0.08%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Conversion disorder		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Suicidal ideation		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device breakage			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	2 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose decreased		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	0 / 5291 (0.00%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain natriuretic peptide increased		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Catheterisation cardiac		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ECG signs of myocardial ischaemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram PR prolongation		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcus test positive		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerular filtration rate decreased		
subjects affected / exposed	2 / 5291 (0.04%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	1 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Glycosylated haemoglobin increased		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella test positive		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test increased		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transaminases increased			
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Airway burns			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer haemorrhage			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	7 / 5291 (0.13%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 7	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Bone contusion		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon injury		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	4 / 5291 (0.08%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dural tear		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	22 / 5291 (0.42%)	13 / 5286 (0.25%)
occurrences causally related to treatment / all	1 / 24	0 / 13
deaths causally related to treatment / all	0 / 2	0 / 0
Femoral neck fracture		
subjects affected / exposed	5 / 5291 (0.09%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	7 / 5291 (0.13%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	4 / 5291 (0.08%)	2 / 5286 (0.04%)
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	12 / 5291 (0.23%)	15 / 5286 (0.28%)
occurrences causally related to treatment / all	0 / 13	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured sacrum		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	7 / 5291 (0.13%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	7 / 5291 (0.13%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hip fracture		
subjects affected / exposed	0 / 5291 (0.00%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	14 / 5291 (0.26%)	16 / 5286 (0.30%)
occurrences causally related to treatment / all	1 / 14	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated parastomal hernia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb fracture		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	4 / 5291 (0.08%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Meniscus injury		
subjects affected / exposed	4 / 5291 (0.08%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Patella fracture		
subjects affected / exposed	2 / 5291 (0.04%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periprocedural myocardial infarction		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thoracic procedure complication		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural shock		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation pneumonitis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	7 / 5291 (0.13%)	8 / 5286 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	13 / 5291 (0.25%)	9 / 5286 (0.17%)
occurrences causally related to treatment / all	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		

subjects affected / exposed	1 / 5291 (0.02%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
Scratch		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin abrasion		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Snake bite		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stab wound		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stomal hernia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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 / 5291 (0.02%)	0 / 5286 (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	3 / 5291 (0.06%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Tendon rupture		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	5 / 5291 (0.09%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haematoma			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	6 / 5291 (0.11%)	3 / 5286 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft occlusion			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound necrosis			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	7 / 5291 (0.13%)	5 / 5286 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			

subjects affected / exposed	7 / 5291 (0.13%)	8 / 5286 (0.15%)
occurrences causally related to treatment / all	1 / 7	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 1
Acute left ventricular failure		
subjects affected / exposed	4 / 5291 (0.08%)	6 / 5286 (0.11%)
occurrences causally related to treatment / all	1 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myocardial infarction		
subjects affected / exposed	48 / 5291 (0.91%)	59 / 5286 (1.12%)
occurrences causally related to treatment / all	1 / 50	1 / 67
deaths causally related to treatment / all	0 / 5	0 / 9
Acute right ventricular failure		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angina pectoris		
subjects affected / exposed	18 / 5291 (0.34%)	25 / 5286 (0.47%)
occurrences causally related to treatment / all	1 / 18	0 / 25
deaths causally related to treatment / all	0 / 1	0 / 0
Angina unstable		
subjects affected / exposed	44 / 5291 (0.83%)	52 / 5286 (0.98%)
occurrences causally related to treatment / all	1 / 47	0 / 58
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve sclerosis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	3 / 5291 (0.06%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Arrhythmia		

subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Arteriosclerosis coronary artery		
subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	34 / 5291 (0.64%)	35 / 5286 (0.66%)
occurrences causally related to treatment / all	0 / 42	1 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	6 / 5291 (0.11%)	12 / 5286 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	5 / 5291 (0.09%)	14 / 5286 (0.26%)
occurrences causally related to treatment / all	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 1
Atrioventricular block second degree		
subjects affected / exposed	5 / 5291 (0.09%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bifascicular block		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	7 / 5291 (0.13%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Bundle branch block		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	5 / 5291 (0.09%)	11 / 5286 (0.21%)
occurrences causally related to treatment / all	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 4	0 / 11
Cardiac disorder		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac failure		
subjects affected / exposed	94 / 5291 (1.78%)	147 / 5286 (2.78%)
occurrences causally related to treatment / all	0 / 107	2 / 183
deaths causally related to treatment / all	0 / 15	0 / 19
Cardiac failure acute		
subjects affected / exposed	18 / 5291 (0.34%)	28 / 5286 (0.53%)
occurrences causally related to treatment / all	0 / 19	1 / 32
deaths causally related to treatment / all	0 / 1	0 / 7
Cardiac failure chronic		

subjects affected / exposed	9 / 5291 (0.17%)	27 / 5286 (0.51%)
occurrences causally related to treatment / all	0 / 10	1 / 32
deaths causally related to treatment / all	0 / 2	0 / 2
Cardiac failure congestive		
subjects affected / exposed	23 / 5291 (0.43%)	46 / 5286 (0.87%)
occurrences causally related to treatment / all	0 / 27	2 / 54
deaths causally related to treatment / all	0 / 2	0 / 6
Cardiac tamponade		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	6 / 5291 (0.11%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 6	0 / 7
Cardiogenic shock		
subjects affected / exposed	6 / 5291 (0.11%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 4
Cardiohepatic syndrome		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic left ventricular failure		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	0 / 5291 (0.00%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	15 / 5291 (0.28%)	22 / 5286 (0.42%)
occurrences causally related to treatment / all	0 / 15	1 / 22
deaths causally related to treatment / all	0 / 1	0 / 1
Coronary artery insufficiency		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery perforation		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	5 / 5291 (0.09%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Heart valve incompetence		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	1 / 5291 (0.02%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 2
Microvascular coronary artery disease		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	24 / 5291 (0.45%)	55 / 5286 (1.04%)
occurrences causally related to treatment / all	1 / 25	0 / 57
deaths causally related to treatment / all	0 / 9	0 / 22
Myocardial ischaemia		
subjects affected / exposed	6 / 5291 (0.11%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal arrhythmia		

subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal rhythm		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	4 / 5291 (0.08%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prosthetic cardiac valve thrombosis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Right ventricular failure		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		

subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	3 / 5291 (0.06%)	6 / 5286 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Subendocardial ischaemia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular extrasystoles		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		

subjects affected / exposed	1 / 5291 (0.02%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ventricular flutter			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	4 / 5291 (0.08%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Auditory nerve disorder			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic neuropathy			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basal ganglia haemorrhage		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Brain injury		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Brain stem infarction		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain stem ischaemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	4 / 5291 (0.08%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda equina syndrome		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar stroke		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Cerebral infarction		
subjects affected / exposed	4 / 5291 (0.08%)	6 / 5286 (0.11%)
occurrences causally related to treatment / all	1 / 4	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebral ischaemia		
subjects affected / exposed	1 / 5291 (0.02%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebrospinal fluid leakage		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	13 / 5291 (0.25%)	16 / 5286 (0.30%)
occurrences causally related to treatment / all	0 / 14	0 / 16
deaths causally related to treatment / all	0 / 3	0 / 2
Cerebrovascular disorder		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		

subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic encephalopathy		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic hyperosmolar coma		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Disturbance in attention		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		

subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyskinesia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	0 / 5291 (0.00%)	8 / 5286 (0.15%)
occurrences causally related to treatment / all	0 / 0	1 / 9
deaths causally related to treatment / all	0 / 0	1 / 5
Haemorrhagic transformation stroke		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		

subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Hypoglycaemic coma		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	2 / 5291 (0.04%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intercostal neuralgia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	29 / 5291 (0.55%)	36 / 5286 (0.68%)
occurrences causally related to treatment / all	0 / 29	0 / 39
deaths causally related to treatment / all	0 / 5	0 / 7
Lacunar infarction		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	2 / 5291 (0.04%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Lumbosacral radiculopathy		
subjects affected / exposed	2 / 5291 (0.04%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke seizure		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ruptured cerebral aneurysm		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Sacral radiculopathy		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		

subjects affected / exposed	5 / 5291 (0.09%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Somnolence		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	26 / 5291 (0.49%)	27 / 5286 (0.51%)
occurrences causally related to treatment / all	2 / 28	1 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Tension headache		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic cerebral infarction		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		

subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	6 / 5291 (0.11%)	14 / 5286 (0.26%)	
occurrences causally related to treatment / all	0 / 6	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar stroke			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood and lymphatic system disorders			
Abdominal lymphadenopathy			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	6 / 5291 (0.11%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anaemia macrocytic			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia of chronic disease		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia of malignant disease		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Antiphospholipid syndrome		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Blood loss anaemia		
subjects affected / exposed	6 / 5291 (0.11%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoprothrombinaemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Iron deficiency anaemia		

subjects affected / exposed	6 / 5291 (0.11%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenitis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic anaemia		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic anaemia		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic infarction		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 5291 (0.04%)	6 / 5286 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle closure glaucoma			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	5 / 5291 (0.09%)	5 / 5286 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal degeneration			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatochalasis			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid cyst		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papilloedema		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal ischaemia			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	4 / 5291 (0.08%)	6 / 5286 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Abdominal pain lower		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	4 / 5291 (0.08%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive duodenitis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		

subjects affected / exposed	3 / 5291 (0.06%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
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	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	5 / 5291 (0.09%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal polyp haemorrhage		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	5 / 5291 (0.09%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal sphincter insufficiency		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ileus paralytic		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia strangulated		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal infarction		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haemorrhage		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		

subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric arterial occlusion		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric vein thrombosis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	0 / 5291 (0.00%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	3 / 5291 (0.06%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stent stenosis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		

subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatitis acute		
subjects affected / exposed	5 / 5291 (0.09%)	12 / 5286 (0.23%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 2
Pancreatitis chronic		
subjects affected / exposed	4 / 5291 (0.08%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis haemorrhagic		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Peptic ulcer		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Portal hypertensive gastropathy		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small intestinal obstruction			
subjects affected / exposed	1 / 5291 (0.02%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated umbilical hernia			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	1 / 5291 (0.02%)	3 / 5286 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	4 / 5291 (0.08%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vomiting			
subjects affected / exposed	2 / 5291 (0.04%)	6 / 5286 (0.11%)	
occurrences causally related to treatment / all	1 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic liver disease			

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct obstruction		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct stenosis		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct stone		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	4 / 5291 (0.08%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Cholecystitis acute		

subjects affected / exposed	10 / 5291 (0.19%)	10 / 5286 (0.19%)
occurrences causally related to treatment / all	0 / 10	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Cholecystitis chronic		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	5 / 5291 (0.09%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder obstruction		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder rupture		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic function abnormal		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis alcoholic		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatorenal syndrome		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocholecystis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumobilia		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cutaneous loxoscelism			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis atopic			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis bullous			

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis contact		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	14 / 5291 (0.26%)	9 / 5286 (0.17%)
occurrences causally related to treatment / all	0 / 16	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ulcer		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Drug eruption		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypersensitivity vasculitis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic skin ulcer		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrobiosis lipidica diabetorum		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic ulcer			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema blister			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	12 / 5291 (0.23%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 14	0 / 4	
deaths causally related to treatment / all	1 / 1	0 / 1	
Urticaria			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	61 / 5291 (1.15%)	52 / 5286 (0.98%)	
occurrences causally related to treatment / all	8 / 64	11 / 57	
deaths causally related to treatment / all	0 / 2	0 / 3	
Anuria			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Calculus bladder		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	14 / 5291 (0.26%)	18 / 5286 (0.34%)
occurrences causally related to treatment / all	3 / 15	0 / 21
deaths causally related to treatment / all	0 / 1	0 / 1
Cystitis glandularis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic end stage renal disease		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic nephropathy		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Dysuria		

subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eosinophilic cystitis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haematuria		
subjects affected / exposed	4 / 5291 (0.08%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive nephropathy		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	2 / 5291 (0.04%)	8 / 5286 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	2 / 5291 (0.04%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive nephropathy		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prerenal failure		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal disorder		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	11 / 5291 (0.21%)	16 / 5286 (0.30%)
occurrences causally related to treatment / all	2 / 12	6 / 17
deaths causally related to treatment / all	0 / 2	0 / 0
Renal haematoma		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal hypertension		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	12 / 5291 (0.23%)	14 / 5286 (0.26%)
occurrences causally related to treatment / all	1 / 12	3 / 14
deaths causally related to treatment / all	0 / 0	0 / 4
Renal tubular necrosis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Stag horn calculus		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	0 / 5291 (0.00%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric obstruction		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		

subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	4 / 5291 (0.08%)	3 / 5286 (0.06%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Empty sella syndrome			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperparathyroidism primary			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary adrenocortical insufficiency			

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 5291 (0.08%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
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	5 / 5291 (0.09%)	4 / 5286 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crowned dens syndrome			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty tophus		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma muscle		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	7 / 5291 (0.13%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic arthropathy		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	9 / 5291 (0.17%)	12 / 5286 (0.23%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporotic fracture		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		

subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	3 / 5291 (0.06%)	2 / 5286 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			

subjects affected / exposed	5 / 5291 (0.09%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess neck		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acarodermatitis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute endocarditis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute sinusitis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	4 / 5291 (0.08%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	1 / 5291 (0.02%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial colitis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial parotitis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial pyelonephritis		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Bacterial sepsis		
subjects affected / exposed	4 / 5291 (0.08%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	0 / 5291 (0.00%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis bacterial		
subjects affected / exposed	2 / 5291 (0.04%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Bronchitis viral		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
COVID-19		
subjects affected / exposed	5 / 5291 (0.09%)	6 / 5286 (0.11%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 3	0 / 3
COVID-19 pneumonia		
subjects affected / exposed	6 / 5291 (0.11%)	5 / 5286 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 2
Campylobacter colitis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	22 / 5291 (0.42%)	17 / 5286 (0.32%)
occurrences causally related to treatment / all	1 / 23	0 / 18
deaths causally related to treatment / all	0 / 1	0 / 0
Cellulitis of male external genital organ		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis B		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	3 / 5291 (0.06%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cryptosporidiosis infection		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cutaneous leishmaniasis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	6 / 5291 (0.11%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis bacterial		
subjects affected / exposed	7 / 5291 (0.13%)	8 / 5286 (0.15%)
occurrences causally related to treatment / all	3 / 7	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis escherichia		
subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis klebsiella		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus colitis		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue haemorrhagic fever		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermo-hypodermatitis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	9 / 5291 (0.17%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	1 / 10	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic gangrene		
subjects affected / exposed	4 / 5291 (0.08%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	5 / 5291 (0.09%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysentery		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		

subjects affected / exposed	6 / 5291 (0.11%)	10 / 5286 (0.19%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia infection		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	3 / 5291 (0.06%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	1 / 3	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Fournier's gangrene		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fungaemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gangrene		
subjects affected / exposed	3 / 5291 (0.06%)	8 / 5286 (0.15%)
occurrences causally related to treatment / all	1 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	18 / 5291 (0.34%)	10 / 5286 (0.19%)
occurrences causally related to treatment / all	1 / 18	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Gastroenteritis viral		
subjects affected / exposed	5 / 5291 (0.09%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Genital abscess		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin infection		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		

subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	2 / 5291 (0.04%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Impetigo		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	2 / 5291 (0.04%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		

subjects affected / exposed	3 / 5291 (0.06%)	7 / 5286 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site abscess		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal fistula infection		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keratitis bacterial		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Liver abscess		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		

subjects affected / exposed	3 / 5291 (0.06%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection bacterial		
subjects affected / exposed	0 / 5291 (0.00%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection viral		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ludwig angina		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastitis bacterial		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site infection		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningoencephalitis bacterial		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metapneumovirus infection		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocarditis infectious		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Necrotising fasciitis		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Nephritis bacterial		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes simplex		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	3 / 5291 (0.06%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	9 / 5291 (0.17%)	8 / 5286 (0.15%)
occurrences causally related to treatment / all	0 / 10	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media bacterial		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian abscess		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paronychia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer helicobacter		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	4 / 5291 (0.08%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		

subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periumbilical abscess		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis streptococcal		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	37 / 5291 (0.70%)	57 / 5286 (1.08%)
occurrences causally related to treatment / all	0 / 40	0 / 62
deaths causally related to treatment / all	0 / 4	0 / 4
Pneumonia adenoviral		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	17 / 5291 (0.32%)	39 / 5286 (0.74%)
occurrences causally related to treatment / all	0 / 17	0 / 42
deaths causally related to treatment / all	0 / 2	0 / 1
Pneumonia haemophilus		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		

subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia klebsiella		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	3 / 5291 (0.06%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pneumonia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	6 / 5291 (0.11%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoas abscess		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		

subjects affected / exposed	3 / 5291 (0.06%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelitis		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	10 / 5291 (0.19%)	10 / 5286 (0.19%)
occurrences causally related to treatment / all	2 / 10	3 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Pyelonephritis acute		
subjects affected / exposed	7 / 5291 (0.13%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	2 / 7	2 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	3 / 5291 (0.06%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Q fever		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		

subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
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 / 5291 (0.02%)	0 / 5286 (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	13 / 5291 (0.25%)	12 / 5286 (0.23%)
occurrences causally related to treatment / all	2 / 13	1 / 12
deaths causally related to treatment / all	0 / 2	0 / 4
Septic shock		
subjects affected / exposed	3 / 5291 (0.06%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Sinusitis aspergillus		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
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	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	4 / 5291 (0.08%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdiaphragmatic abscess		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Suspected COVID-19		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Systemic infection		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic viral infection		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheitis		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (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	3 / 5291 (0.06%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection bacterial		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	8 / 5291 (0.15%)	10 / 5286 (0.19%)
occurrences causally related to treatment / all	3 / 8	5 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	9 / 5291 (0.17%)	13 / 5286 (0.25%)
occurrences causally related to treatment / all	2 / 9	2 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection fungal		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	12 / 5291 (0.23%)	10 / 5286 (0.19%)
occurrences causally related to treatment / all	4 / 14	7 / 10
deaths causally related to treatment / all	0 / 1	1 / 1
Vestibular neuronitis		

subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	2 / 5291 (0.04%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral myocarditis			
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cellulitis			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	6 / 5291 (0.11%)	7 / 5286 (0.13%)	
occurrences causally related to treatment / all	0 / 6	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	5 / 5291 (0.09%)	9 / 5286 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			

subjects affected / exposed	17 / 5291 (0.32%)	25 / 5286 (0.47%)
occurrences causally related to treatment / all	0 / 21	2 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	11 / 5291 (0.21%)	4 / 5286 (0.08%)
occurrences causally related to treatment / all	1 / 11	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	2 / 5291 (0.04%)	6 / 5286 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 5291 (0.02%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	10 / 5291 (0.19%)	23 / 5286 (0.44%)
occurrences causally related to treatment / all	0 / 11	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	0 / 5291 (0.00%)	3 / 5286 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		

subjects affected / exposed	14 / 5291 (0.26%)	11 / 5286 (0.21%)
occurrences causally related to treatment / all	1 / 14	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperuricaemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoalbuminaemia		
subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	35 / 5291 (0.66%)	31 / 5286 (0.59%)
occurrences causally related to treatment / all	11 / 39	9 / 37
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	2 / 5291 (0.04%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	3 / 5291 (0.06%)	9 / 5286 (0.17%)
occurrences causally related to treatment / all	1 / 3	2 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
Hypovolaemia		
subjects affected / exposed	1 / 5291 (0.02%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Increased insulin requirement		

subjects affected / exposed	1 / 5291 (0.02%)	0 / 5286 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	14 / 5291 (0.26%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	2 / 14	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic disorder		
subjects affected / exposed	0 / 5291 (0.00%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic syndrome		
subjects affected / exposed	2 / 5291 (0.04%)	2 / 5286 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	1 / 5291 (0.02%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	3 / 5291 (0.06%)	1 / 5286 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

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

Non-serious adverse events	Sotagliflozin	Placebo	
Total subjects affected by non-serious adverse events subjects affected / exposed	705 / 5291 (13.32%)	609 / 5286 (11.52%)	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	373 / 5291 (7.05%) 450	253 / 5286 (4.79%) 295	
Metabolism and nutrition disorders Hypoglycaemia subjects affected / exposed occurrences (all)	380 / 5291 (7.18%) 1022	395 / 5286 (7.47%) 1066	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The study was terminated prematurely due to financial reasons and Covid-19 pandemic.

Notes: