



Clinical trial results:

A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease

Summary

EudraCT number	2015-000990-11
Trial protocol	DK SE GB AT CZ ES FI PT BE NL FR DE LT PL GR RO IE SK IT
Global end of trial date	14 April 2020

Results information

Result version number	v1 (current)
This version publication date	22 April 2021
First version publication date	22 April 2021

Trial information

Trial identification

Sponsor protocol code	16244
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02540993
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser Wilhelm Allee, Leverkusen, Germany, D-51368
Public contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.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	14 April 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 April 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to demonstrate whether, in addition to standard of care, finerenone is superior to placebo in delaying the progression of kidney disease, as measured by the composite endpoint of time to first occurrence of kidney failure, a sustained decrease of estimated glomerular filtration rate (eGFR) $\geq 40\%$ from baseline over at least 4 weeks, or renal death.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and the International Council for Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent was read by and explained to all the subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy:

Standard of care: individual maximum tolerated labeled dose of either an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB) (but not both)

Evidence for comparator: -

Actual start date of recruitment	17 September 2015
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	Austria: 62
Country: Number of subjects enrolled	Belgium: 54
Country: Number of subjects enrolled	Bulgaria: 225
Country: Number of subjects enrolled	Switzerland: 10
Country: Number of subjects enrolled	Czechia: 99
Country: Number of subjects enrolled	Germany: 88
Country: Number of subjects enrolled	Denmark: 111
Country: Number of subjects enrolled	Spain: 260
Country: Number of subjects enrolled	Finland: 62
Country: Number of subjects enrolled	France: 64
Country: Number of subjects enrolled	United Kingdom: 67
Country: Number of subjects enrolled	Greece: 48
Country: Number of subjects enrolled	Hungary: 140
Country: Number of subjects enrolled	Ireland: 5

Country: Number of subjects enrolled	Italy: 206
Country: Number of subjects enrolled	Lithuania: 9
Country: Number of subjects enrolled	Netherlands: 72
Country: Number of subjects enrolled	Norway: 26
Country: Number of subjects enrolled	Poland: 112
Country: Number of subjects enrolled	Portugal: 130
Country: Number of subjects enrolled	Romania: 59
Country: Number of subjects enrolled	Russian Federation: 263
Country: Number of subjects enrolled	Slovakia: 7
Country: Number of subjects enrolled	Sweden: 34
Country: Number of subjects enrolled	Turkey: 72
Country: Number of subjects enrolled	Ukraine: 73
Country: Number of subjects enrolled	Canada: 107
Country: Number of subjects enrolled	Puerto Rico: 13
Country: Number of subjects enrolled	United States: 824
Country: Number of subjects enrolled	China: 372
Country: Number of subjects enrolled	Hong Kong: 61
Country: Number of subjects enrolled	Israel: 252
Country: Number of subjects enrolled	Japan: 415
Country: Number of subjects enrolled	Korea, Republic of: 138
Country: Number of subjects enrolled	Malaysia: 77
Country: Number of subjects enrolled	Philippines: 45
Country: Number of subjects enrolled	Singapore: 19
Country: Number of subjects enrolled	Thailand: 36
Country: Number of subjects enrolled	Taiwan: 111
Country: Number of subjects enrolled	Vietnam: 53
Country: Number of subjects enrolled	Argentina: 84
Country: Number of subjects enrolled	Brazil: 176
Country: Number of subjects enrolled	Chile: 31
Country: Number of subjects enrolled	Colombia: 182
Country: Number of subjects enrolled	Mexico: 120
Country: Number of subjects enrolled	Australia: 63
Country: Number of subjects enrolled	New Zealand: 38
Country: Number of subjects enrolled	South Africa: 99
Worldwide total number of subjects	5674
EEA total number of subjects	1940

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)	2379
From 65 to 84 years	3252
85 years and over	43

Subject disposition

Recruitment

Recruitment details:

Study was conducted at multiple centers in 48 countries/regions between 17-SEP-2015 (first subject first visit) and 14-APR-2020 (last subject last visit).

Pre-assignment

Screening details:

Overall, 13911 subjects were screened. Of them, 8177 subjects were screening failures and 5734 subjects were randomized. 60 subjects were prospectively excluded from the analyses due to GCP violations resulting in 5674 subjects in the full analysis set. 16 subjects did not take any study drug resulting in 5658 subjects who received study treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Finerenone

Arm description:

Subjects received finerenone 10 mg or 20 mg once daily in addition to standard of care therapy

Arm type	Experimental
Investigational medicinal product name	Finerenone
Investigational medicinal product code	BAY94-8862
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet; starting dose at 10 mg for subjects with an eGFR between 25 to < 60 mL/min/1.73m² at the Screening Visit; starting dose at 20 mg for subjects with an eGFR ≥ 60 mL/min/1.73m² at the Screening Visit; dose could be up-titrated from Month 1 onwards or down-titrated at any time during the study; once daily in the morning, until the trial was completed provided there were no safety grounds for discontinuing treatment

Arm title	Placebo
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Arm description:

Subjects received matching placebo once daily in addition to standard of care therapy

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

Dosage and administration details:

Matching placebo, oral tablet, once daily in the morning, until the trial was completed provided there were no safety grounds for discontinuing treatment

Number of subjects in period 1	Finerenone	Placebo
Started	2833	2841
Treated	2827	2831 ^[1]
Completed	2824	2832
Not completed	9	9
Consent withdrawn by subject	4	6
Lost to follow-up	5	3

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Subjects were followed up regardless of having started treatment or not, and study completion (completion of period 1) is independent of administration of study treatment. A subject was considered as having completed the study if there was a contact with the subject after the end-of-study (EOS) notification or if the subject died.

Baseline characteristics

Reporting groups

Reporting group title	Finerenone
Reporting group description:	
Subjects received finerenone 10 mg or 20 mg once daily in addition to standard of care therapy	
Reporting group title	Placebo
Reporting group description:	
Subjects received matching placebo once daily in addition to standard of care therapy	

Reporting group values	Finerenone	Placebo	Total
Number of subjects	2833	2841	5674
Age Categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	65.44	65.67	-
standard deviation	± 8.94	± 9.16	-
Gender Categorical			
Units: Subjects			
Female	880	811	1691
Male	1953	2030	3983
Race			
Units: Subjects			
White	1777	1815	3592
Black or African American	140	124	264
Asian	717	723	1440
American Indian or Alaska Native	78	76	154
Native Hawaiian or Other Pacific Islander	11	7	18
Not Reported	9	10	19
Multiple	101	86	187
Ethnicity			
Units: Subjects			
Not Hispanic or Latino	2376	2397	4773
Hispanic or Latino	447	431	878
Not Reported	10	13	23
Urinary albumin-to-creatinine ratio (UACR)			
Units: milligram/gram (mg/g)			
median	832.72	867.01	-
inter-quartile range (Q1-Q3)	441.00 to 1628.14	453.11 to 1644.58	-
Estimated glomerular filtration rate (eGFR)			
Units: mL/min/1.73m ²			
arithmetic mean	44.36	44.32	-
standard deviation	± 12.54	± 12.57	-

End points

End points reporting groups

Reporting group title	Finerenone
Reporting group description:	Subjects received finerenone 10 mg or 20 mg once daily in addition to standard of care therapy
Reporting group title	Placebo
Reporting group description:	Subjects received matching placebo once daily in addition to standard of care therapy
Subject analysis set title	Full analysis set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	The FAS comprised all randomized subjects (except those with critical GCP violations)

Primary: The first occurrence of the composite endpoint of onset of kidney failure, a sustained decrease of eGFR \geq 40% from baseline over at least 4 weeks, or renal death

End point title	The first occurrence of the composite endpoint of onset of kidney failure, a sustained decrease of eGFR \geq 40% from baseline over at least 4 weeks, or renal death
End point description:	Count of subjects and time from randomization to the first occurrence of the primary renal composite outcome, onset of kidney failure, a sustained decrease of eGFR \geq 40% from baseline over at least 4 weeks, or renal death were evaluated. Number of subjects with the outcome event is reported as descriptive result and hazard ratio is reported as statistical analysis.
End point type	Primary
End point timeframe:	From randomization up until the first occurrence of the primary renal composite endpoint, or censoring at the end of the study, with an average follow-up time of 32 months

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2833	2841		
Units: Subjects				
number (not applicable)	504	600		

Statistical analyses

Statistical analysis title	Primary renal composite endpoint
Statistical analysis description:	A stratified Cox proportional hazards regression model was used to provide a point estimate of the hazard ratio and a corresponding two-sided 95% confidence interval.
Comparison groups	Finerenone v Placebo

Number of subjects included in analysis	5674
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0014 ^[1]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.825
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.732
upper limit	0.928

Notes:

[1] - P-value from stratified log-rank test. Significance was considered to be achieved if p-value ≤ 0.03282695.

Secondary: The first occurrence of the composite endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for heart failure

End point title	The first occurrence of the composite endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for heart failure
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End point description:

Count of subjects and time from randomization to the first occurrence of the key secondary cardiovascular (CV) composite outcome, CV death, non-fatal myocardial infarction (MI), non-fatal stroke, or hospitalization for heart failure were evaluated. Number of subjects with the outcome event is reported as descriptive result and hazard ratio is reported as statistical analysis.

End point type	Secondary
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End point timeframe:

From randomization up until the first occurrence of the key secondary CV composite endpoint, or censoring at the end of the study, with an average of 32 months

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2833	2841		
Units: Subjects				
number (not applicable)	367	420		

Statistical analyses

Statistical analysis title	CV composite endpoint
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Statistical analysis description:

A stratified Cox proportional hazards regression model was used to provide a point estimate of the hazard ratio and a corresponding two-sided 95% confidence interval.

Comparison groups	Finerenone v Placebo
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Number of subjects included in analysis	5674
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0339 [2]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.747
upper limit	0.989

Notes:

[2] - P-value from stratified log-rank test. Significance was considered to be achieved if p-value ≤ 0.04967388.

Secondary: All-cause mortality

End point title	All-cause mortality
End point description:	
Count of subjects and time from randomization until death due to any cause were evaluated. Number of subjects with outcome death is reported as descriptive result and hazard ratio is reported as statistical analysis.	
End point type	Secondary
End point timeframe:	
From randomization up until death due to any cause, or censoring at the end of the study, with an average of 32 months	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2833	2841		
Units: Subjects				
number (not applicable)	219	244		

Statistical analyses

Statistical analysis title	All-cause mortality
Statistical analysis description:	
A stratified Cox proportional hazards regression model was used to provide a point estimate of the hazard ratio and a corresponding two-sided 95% confidence interval.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	5674
Analysis specification	Pre-specified
Analysis type	superiority ^[3]
P-value	= 0.2348 [4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.895

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.746
upper limit	1.075

Notes:

[3] - As treatment effect on both primary and key secondary endpoint was significant, other secondary efficacy endpoints (i.e. all-cause mortality, all-cause hospitalization, change in UACR from baseline to Month 4, and secondary renal composite endpoint) were tested hierarchically, starting with all-cause mortality. As treatment effect on all-cause mortality was not significant, all other endpoints were tested in an exploratory manner.

[4] - P-value from stratified log-rank test. Significance was considered to be achieved if p-value \leq 0.04967388.

Secondary: All-cause hospitalization

End point title	All-cause hospitalization
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End point description:

Count of subjects and time from randomization to the first occurrence of a hospitalization event were evaluated. Number of subjects with the event is reported as descriptive result and hazard ratio is reported as statistical analysis.

End point type	Secondary
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End point timeframe:

From randomization up until the first occurrence of the hospitalization due to any cause, or censoring at the end of the study, with an average of 32 months

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2833	2841		
Units: Subjects				
number (not applicable)	1263	1321		

Statistical analyses

Statistical analysis title	All-cause hospitalization
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Statistical analysis description:

A stratified Cox proportional hazards regression model was used to provide a point estimate of the hazard ratio and a corresponding two-sided 95% confidence interval.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	5674
Analysis specification	Pre-specified
Analysis type	superiority ^[5]
P-value	= 0.1623 ^[6]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.946

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.876
upper limit	1.022

Notes:

[5] - As treatment effect on both primary and key secondary endpoint was significant, other secondary efficacy endpoints (i.e. all-cause mortality, all-cause hospitalization, change in UACR from baseline to Month 4, and secondary renal composite endpoint) were tested hierarchically, starting with all-cause mortality. As treatment effect on all-cause mortality was not significant, all other endpoints were tested in an exploratory manner.

[6] - P-value from stratified log-rank test.

Secondary: Change in urinary albumin-to-creatinine ratio (UACR) from baseline to Month 4

End point title	Change in urinary albumin-to-creatinine ratio (UACR) from baseline to Month 4
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End point description:

First morning void urine samples were collected to evaluate the urinary albumin-to-creatinine ratio (UACR). Month 4 was the visit closest to day 120 within a time window of 120 ± 30 days after randomization. If no measurements were available in this time window, the subject was excluded from this analysis. Ratio of UACR at Month 4 to UACR at baseline is reported as the change. The analysis was performed on the subjects in FAS with measurements available within the time window of Month 4.

End point type	Secondary
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End point timeframe:

From baseline up until Month 4

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2711	2705		
Units: Ratio				
least squares mean (confidence interval 95%)	0.655 (0.637 to 0.673)	0.952 (0.927 to 0.979)		

Statistical analyses

Statistical analysis title	Change in UACR from baseline to Month 4
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	5416
Analysis specification	Pre-specified
Analysis type	superiority ^[7]
P-value	< 0.0001 ^[8]
Method	ANCOVA
Parameter estimate	Ratio of least squares means
Point estimate	0.688

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.662
upper limit	0.715

Notes:

[7] - As treatment effect on both primary and key secondary endpoint was significant, other secondary efficacy endpoints (i.e. all-cause mortality, all-cause hospitalization, change in UACR from baseline to Month 4, and secondary renal composite endpoint) were tested hierarchically, starting with all-cause mortality. As treatment effect on all-cause mortality was not significant, all other endpoints were tested in an exploratory manner.

[8] - P-value from F-test of equal means between the treatment groups.

Secondary: The first occurrence of the composite endpoint of onset of kidney failure, a sustained decrease in eGFR of $\geq 57\%$ from baseline over at least 4 weeks, or renal death

End point title	The first occurrence of the composite endpoint of onset of kidney failure, a sustained decrease in eGFR of $\geq 57\%$ from baseline over at least 4 weeks, or renal death
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End point description:

Count of subjects and time from randomization to the first occurrence of the secondary renal composite outcome, onset of kidney failure, a sustained decrease in eGFR of $\geq 57\%$ from baseline over at least 4 weeks, or renal death were evaluated. Number of subjects with the outcome event is reported as descriptive result and hazard ratio is reported as statistical analysis.

End point type	Secondary
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End point timeframe:

From randomization up until the first occurrence of the composite primary endpoint, or censoring at the end of the study, with an average of 32 months

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2833	2841		
Units: Subjects				
number (not applicable)	252	326		

Statistical analyses

Statistical analysis title	Secondary renal composite endpoint
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Statistical analysis description:

A stratified Cox proportional hazards regression model was used to provide a point estimate of the hazard ratio and a corresponding two-sided 95% confidence interval.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	5674
Analysis specification	Pre-specified
Analysis type	superiority ^[9]
P-value	= 0.0012 ^[10]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.763

Confidence interval

level	95 %
sides	2-sided
lower limit	0.648
upper limit	0.9

Notes:

[9] - As treatment effect on both primary and key secondary endpoint was significant, other secondary efficacy endpoints (i.e. all-cause mortality, all-cause hospitalization, change in UACR from baseline to Month 4, and secondary renal composite endpoint) were tested hierarchically, starting with all-cause mortality. As treatment effect on all-cause mortality was not significant, all other endpoints were tested in an exploratory manner.

[10] - P-value from stratified log-rank test.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

After the first dose of study drug up to 3 days after any temporary or permanent interruption of study drug, with an average treatment duration of 27 months

Adverse event reporting additional description:

Adverse event reporting for the numbers of deaths (all causes) considers all deaths in the safety analysis set (comprised all randomized subjects who took at least 1 dose of study drug [except those with critical GCP violations]) that occurred at any time during the study after the first dose of study drug (with an average duration of 32 months).

Assessment type	Non-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	Finerenone
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Reporting group description:

Subjects received finerenone 10 mg or 20 mg once daily in addition to standard of care therapy

Reporting group title	Placebo
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Reporting group description:

Subjects received matching placebo once daily in addition to standard of care therapy

Serious adverse events	Finerenone	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	902 / 2827 (31.91%)	971 / 2831 (34.30%)	
number of deaths (all causes)	220	249	
number of deaths resulting from adverse events	31	51	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			

subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	2 / 2827 (0.07%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Adenoma benign		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma stage IV		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.07%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder squamous cell carcinoma stage unspecified		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's disease		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	4 / 2827 (0.14%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Breast neoplasm		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	4 / 2827 (0.14%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Colon cancer stage IV		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma recurrent		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroadenoma of breast		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrosarcoma		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric cancer		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal carcinoma		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haemangioma		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypergammaglobulinaemia benign monoclonal		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo maligna		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung squamous cell carcinoma stage IV		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	0 / 2827 (0.00%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to lung		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to spine		

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal cavity cancer		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm prostate		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma of the skin		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	3 / 2827 (0.11%)	0 / 2831 (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	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal cancer		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatic carcinoma metastatic		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Penile cancer		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cancer		

subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Small cell lung cancer			
subjects affected / exposed	0 / 2827 (0.00%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 of skin			
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage			

unspecified			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage 0			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	3 / 2827 (0.11%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stromal tumour			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spleen			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer metastatic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal cancer metastatic		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Breast cancer metastatic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected neoplasm		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cancer pain		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder adenocarcinoma		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm malignant		

subjects affected / exposed	9 / 2827 (0.32%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
Metastases to central nervous system		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma stage IV		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small cell lung cancer metastatic		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Prostate cancer		
subjects affected / exposed	13 / 2827 (0.46%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 13	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Monoclonal gammopathy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign pancreatic neoplasm		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant urinary tract neoplasm		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland neoplasm		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic neoplasm		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue neoplasm		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral neoplasm		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sarcoma metastatic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tumour rupture		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatocellular carcinoma		
subjects affected / exposed	3 / 2827 (0.11%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Hepatobiliary cancer		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		

subjects affected / exposed	3 / 2827 (0.11%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiomyofibroblastoma			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure fluctuation			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism venous		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	15 / 2827 (0.53%)	23 / 2831 (0.81%)
occurrences causally related to treatment / all	0 / 16	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	4 / 2827 (0.14%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	7 / 2827 (0.25%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	3 / 7	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Intermittent claudication		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	4 / 2827 (0.14%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 4	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Temporal arteritis		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thromboangiitis obliterans		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		

subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	4 / 2827 (0.14%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		

subjects affected / exposed	2 / 2827 (0.07%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive urgency		
subjects affected / exposed	4 / 2827 (0.14%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Venous occlusion		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microangiopathy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	0 / 2827 (0.00%)	6 / 2831 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		

subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Aortic valve replacement			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula operation			
subjects affected / exposed	3 / 2827 (0.11%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery bypass			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	1 / 2827 (0.04%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodialysis			

subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	3 / 2827 (0.11%)	6 / 2831 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterectomy			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insertion of ambulatory peritoneal catheter			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	4 / 2827 (0.14%)	6 / 2831 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leg amputation			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metatarsal excision			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myomectomy			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroidectomy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Physiotherapy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pterygium operation		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinoplasty		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal decompression		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tenotomy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toe amputation		
subjects affected / exposed	4 / 2827 (0.14%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Transurethral prostatectomy		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia repair		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine prolapse repair		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vitrectomy		
subjects affected / exposed	1 / 2827 (0.04%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenectomy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac pacemaker replacement		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implantable defibrillator insertion		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary angioplasty		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fusion surgery		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radical prostatectomy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus management		
subjects affected / exposed	3 / 2827 (0.11%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transurethral bladder resection		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac rehabilitation therapy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Continuous positive airway pressure		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephroureterectomy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreaticosplenectomy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polypectomy		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Maxillofacial operation			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal transplant			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus operation			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck operation			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral dilation procedure			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc operation			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rehabilitation therapy			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dialysis device insertion			

subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin neoplasm excision		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot operation		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Amputation		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthrodesis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colectomy		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon operation		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye operation		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oophorectomy		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatectomy		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrectomy		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric bypass		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocele operation		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal operation		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nail operation		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin graft		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal operation		

subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound treatment		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder polypectomy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract operation		
subjects affected / exposed	4 / 2827 (0.14%)	12 / 2831 (0.42%)
occurrences causally related to treatment / all	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Aneurysm repair		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bowel preparation		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopexy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraocular lens implant		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal fixation of spine			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stent removal			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric banding reversal			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Therapeutic nerve ablation			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery bypass			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal polypectomy			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic surgery			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest discomfort		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	13 / 2827 (0.46%)	18 / 2831 (0.64%)
occurrences causally related to treatment / all	0 / 15	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	2 / 2827 (0.07%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 4
Fatigue		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised oedema		
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothermia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mass		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		
subjects affected / exposed	4 / 2827 (0.14%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	8 / 2827 (0.28%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	4 / 2827 (0.14%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue inflammation		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Swelling face		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia pain		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema due to renal disease			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device intolerance			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Immune system disorders			
Drug hypersensitivity			

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Social stay hospitalisation			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	5 / 2827 (0.18%)	10 / 2831 (0.35%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Uterine haemorrhage			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial thickening			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular mass			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	3 / 2827 (0.11%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	6 / 2827 (0.21%)	15 / 2831 (0.53%)	
occurrences causally related to treatment / all	0 / 6	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 2	

Aspiration			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	1 / 2827 (0.04%)	6 / 2831 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchitis chronic			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	14 / 2827 (0.50%)	12 / 2831 (0.42%)	
occurrences causally related to treatment / all	0 / 21	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 1	
Chronic respiratory failure			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	8 / 2827 (0.28%)	7 / 2831 (0.25%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea at rest			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Laryngeal oedema		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal stenosis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal oedema		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	4 / 2827 (0.14%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	1 / 2827 (0.04%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	3 / 2827 (0.11%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	8 / 2827 (0.28%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	1 / 2827 (0.04%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	5 / 2827 (0.18%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0
Sleep apnoea syndrome		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord polyp		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wheezing		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Restrictive pulmonary disease		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord cyst		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopneumopathy		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal dysplasia			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottic cyst			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal mass			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hilum mass			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Insomnia		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Suicide attempt		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	1 / 2827 (0.04%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device malfunction			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	2 / 2827 (0.07%)	4 / 2831 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	4 / 2827 (0.14%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			

subjects affected / exposed	2 / 2827 (0.07%)	9 / 2831 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	12 / 2827 (0.42%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 14	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	1 / 2827 (0.04%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic function abnormal		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis alcoholic		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic lesion			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biopsy kidney		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatine phosphokinase increased		
subjects affected / exposed	0 / 2827 (0.00%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatine phosphokinase MB increased		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatinine increased		
subjects affected / exposed	1 / 2827 (0.04%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 1	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colonoscopy		

subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endoscopy small intestine		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	5 / 2827 (0.18%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate increased		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Protein urine present		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac pacemaker evaluation		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Computerised tomogram abdomen		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin T increased		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Light chain analysis increased		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anticoagulation drug level above therapeutic		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriogram		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory marker increased			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza A virus test positive			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular examination			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arteriogram			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiocardiogram			
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			

subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acetabulum fracture		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol poisoning		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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 / 2827 (0.25%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Back injury		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dislocation of vertebra		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	2 / 2827 (0.07%)	6 / 2831 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	7 / 2827 (0.25%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	6 / 2827 (0.21%)	9 / 2831 (0.32%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Heat stroke		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	6 / 2827 (0.21%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Humerus fracture		
subjects affected / exposed	4 / 2827 (0.14%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning deliberate		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation proctitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	3 / 2827 (0.11%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	5 / 2827 (0.18%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		

subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue injury		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury cervical		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Spinal fracture		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	4 / 2827 (0.14%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Tendon injury		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		

subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic fracture		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle strain		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound necrosis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammation of wound		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula site complication		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post concussion syndrome		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site haematoma		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	3 / 2827 (0.11%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament injury		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	4 / 2827 (0.14%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt malfunction		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural inflammation		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wound dehiscence		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac contusion		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated incisional hernia			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access malfunction			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular procedural complication			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Factor VIII deficiency			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Truncus arteriosus persistent			

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 2827 (0.00%)	5 / 2831 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			

subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	1 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac asthma			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 2827 (0.04%)	10 / 2831 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	0 / 2827 (0.00%)	8 / 2831 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiogenic shock		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	8 / 2827 (0.28%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial ischaemia		
subjects affected / exposed	0 / 2827 (0.00%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		

subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve calcification		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute coronary syndrome		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bifascicular block		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve disease		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute left ventricular failure		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiorenal syndrome		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic mitral regurgitation			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Alcohol induced persisting dementia			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brown-Sequard syndrome			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebral infarction		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular disorder		
subjects affected / exposed	4 / 2827 (0.14%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cranial nerve palsies multiple		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	6 / 2827 (0.21%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	6 / 2827 (0.21%)	10 / 2831 (0.35%)
occurrences causally related to treatment / all	0 / 6	2 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Drop attacks		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		

subjects affected / exposed	0 / 2827 (0.00%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lethargy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	4 / 2827 (0.14%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post herpetic neuralgia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	4 / 2827 (0.14%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	4 / 2827 (0.14%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	3 / 2827 (0.11%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Syncope		

subjects affected / exposed	12 / 2827 (0.42%)	22 / 2831 (0.78%)
occurrences causally related to treatment / all	0 / 12	2 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain oedema		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Carotid artery occlusion		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery occlusion		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arachnoid cyst		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Balance disorder		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar infarction		

subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paresis			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodegenerative disorder			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral disorder			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroglycopenia			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral vasoconstriction			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononeuropathy			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid arteriosclerosis			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral microangiopathy			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral vascular occlusion			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke epilepsy			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemianaesthesia			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiopathic neuropathy			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	14 / 2827 (0.50%)	19 / 2831 (0.67%)	
occurrences causally related to treatment / all	0 / 14	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	5 / 2827 (0.18%)	6 / 2831 (0.21%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic anaemia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytopenia		

subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic anaemia			
subjects affected / exposed	0 / 2827 (0.00%)	5 / 2831 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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			
Deafness neurosensory			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear pain			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	3 / 2827 (0.11%)	4 / 2831 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Blindness			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	19 / 2827 (0.67%)	12 / 2831 (0.42%)	
occurrences causally related to treatment / all	0 / 22	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract subcapsular			

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinal oedema		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	3 / 2827 (0.11%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Ectropion		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye disorder		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemorrhage		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	6 / 2827 (0.21%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lens dislocation		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Optic disc haemorrhage		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papilloedema		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pterygium		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	4 / 2827 (0.14%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	6 / 2827 (0.21%)	7 / 2831 (0.25%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhegmatogenous retinal detachment			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tractional retinal detachment			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	6 / 2827 (0.21%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	2 / 2827 (0.07%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Change of bowel habit		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	3 / 2827 (0.11%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	0 / 2827 (0.00%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		

subjects affected / exposed	3 / 2827 (0.11%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dental caries		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	7 / 2827 (0.25%)	6 / 2831 (0.21%)
occurrences causally related to treatment / all	1 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea haemorrhagic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal polyp		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	3 / 2827 (0.11%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Duodenal ulcer perforation		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Duodenitis haemorrhagic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		

subjects affected / exposed	13 / 2827 (0.46%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 16	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	1 / 2827 (0.04%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal angina		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	3 / 2827 (0.11%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	3 / 2827 (0.11%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal achalasia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer haemorrhage		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	7 / 2827 (0.25%)	8 / 2831 (0.28%)
occurrences causally related to treatment / all	1 / 8	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatitis chronic		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	6 / 2827 (0.21%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland calculus		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	2 / 2827 (0.07%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Vomiting		
subjects affected / exposed	3 / 2827 (0.11%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	6 / 2827 (0.21%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		

subjects affected / exposed	5 / 2827 (0.18%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Chilaiditi's syndrome		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous pancreatitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal haemorrhage		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal strangulated hernia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric mucosal lesion			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic duct stenosis			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Functional gastrointestinal disorder			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal mass			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal fluid collection			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal vascular malformation haemorrhagic			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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			
Actinic keratosis			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			

subjects affected / exposed	3 / 2827 (0.11%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blister		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Decubitus ulcer		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis bullous		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis herpetiformis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug eruption		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ecchymosis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkeratosis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ingrowing nail		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parapsoriasis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigoid		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Purpura		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin disorder			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	9 / 2827 (0.32%)	16 / 2831 (0.57%)	
occurrences causally related to treatment / all	0 / 10	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic ulcer			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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	13 / 2827 (0.46%)	18 / 2831 (0.64%)	
occurrences causally related to treatment / all	0 / 16	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Azotaemia			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chromaturia		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis ulcerative		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerular vascular disorder		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	3 / 2827 (0.11%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intercapillary glomerulosclerosis		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	6 / 2827 (0.21%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrosclerosis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	3 / 2827 (0.11%)	9 / 2831 (0.32%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Nocturia		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		

subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
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 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	7 / 2827 (0.25%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	2 / 7	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haemorrhage		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular acidosis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		

subjects affected / exposed	6 / 2827 (0.21%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder polyp		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive nephropathy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cyst		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract obstruction		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	18 / 2827 (0.64%)	16 / 2831 (0.57%)
occurrences causally related to treatment / all	0 / 23	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		

subjects affected / exposed	8 / 2827 (0.28%)	8 / 2831 (0.28%)
occurrences causally related to treatment / all	0 / 8	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	12 / 2827 (0.42%)	22 / 2831 (0.78%)
occurrences causally related to treatment / all	1 / 12	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute kidney injury		
subjects affected / exposed	56 / 2827 (1.98%)	51 / 2831 (1.80%)
occurrences causally related to treatment / all	10 / 63	6 / 55
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder outlet obstruction		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perinephritis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	5 / 2827 (0.18%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Subcapsular renal haematoma		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary-dependent Cushing's syndrome			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2827 (0.00%)	5 / 2831 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Back disorder			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
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	3 / 2827 (0.11%)	5 / 2831 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	5 / 2827 (0.18%)	2 / 2831 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	4 / 2827 (0.14%)	7 / 2831 (0.25%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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 / 2827 (0.00%)	1 / 2831 (0.04%)
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	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	11 / 2827 (0.39%)	8 / 2831 (0.28%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthropathy		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		

subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal disorder		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	7 / 2827 (0.25%)	13 / 2831 (0.46%)
occurrences causally related to treatment / all	0 / 7	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma muscle		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Connective tissue inflammation		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis of jaw		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue necrosis		

subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal instability			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb mass			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atypical pneumonia			
subjects affected / exposed	0 / 2827 (0.00%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			

subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	9 / 2827 (0.32%)	13 / 2831 (0.46%)
occurrences causally related to treatment / all	0 / 9	1 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carbuncle		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	26 / 2827 (0.92%)	22 / 2831 (0.78%)
occurrences causally related to treatment / all	0 / 30	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic sinusitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	3 / 2827 (0.11%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ear infection		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endophthalmitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	1 / 2827 (0.04%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottitis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		

subjects affected / exposed	11 / 2827 (0.39%)	14 / 2831 (0.49%)
occurrences causally related to treatment / all	0 / 11	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
Fournier's gangrene		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	5 / 2827 (0.18%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Gastroenteritis		
subjects affected / exposed	9 / 2827 (0.32%)	13 / 2831 (0.46%)
occurrences causally related to treatment / all	0 / 9	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	3 / 2827 (0.11%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis viral		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		

subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	4 / 2827 (0.14%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	1 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	7 / 2827 (0.25%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Labyrinthitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leptospirosis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	2 / 2827 (0.07%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		

subjects affected / exposed	7 / 2827 (0.25%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	5 / 2827 (0.18%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal candidiasis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	14 / 2827 (0.50%)	12 / 2831 (0.42%)
occurrences causally related to treatment / all	0 / 14	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1
Osteomyelitis chronic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paronychia		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	70 / 2827 (2.48%)	103 / 2831 (3.64%)
occurrences causally related to treatment / all	0 / 75	0 / 115
deaths causally related to treatment / all	0 / 1	0 / 5
Pneumonia respiratory syncytial viral		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic abscess		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Pyelonephritis		
subjects affected / exposed	7 / 2827 (0.25%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	5 / 2827 (0.18%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyonephrosis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		

subjects affected / exposed	15 / 2827 (0.53%)	17 / 2831 (0.60%)
occurrences causally related to treatment / all	0 / 15	0 / 18
deaths causally related to treatment / all	0 / 1	0 / 3
Septic shock		
subjects affected / exposed	3 / 2827 (0.11%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 4
Sinusitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic abscess		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Subcutaneous abscess		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	0 / 2827 (0.00%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urethritis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
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	21 / 2827 (0.74%)	23 / 2831 (0.81%)
occurrences causally related to treatment / all	0 / 22	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral pericarditis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral tracheitis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	4 / 2827 (0.14%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oral infection		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	5 / 2827 (0.18%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelocystitis		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillitis		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess limb		
subjects affected / exposed	3 / 2827 (0.11%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burn infection		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall abscess		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (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	5 / 2827 (0.18%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Febrile infection		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	3 / 2827 (0.11%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal tuberculosis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		

subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viraemia		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute hepatitis B		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	0 / 2827 (0.00%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	4 / 2827 (0.14%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal abscess		

subjects affected / exposed	2 / 2827 (0.07%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	1 / 2827 (0.04%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Borrelia infection		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes ophthalmic		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis bacterial		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection staphylococcal		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		

subjects affected / exposed	3 / 2827 (0.11%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Infective spondylitis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma site infection		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Derma-hypodermatitis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
H1N1 influenza		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		

subjects affected / exposed	0 / 2827 (0.00%)	3 / 2831 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected seroma			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site joint infection			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bite			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephritis bacterial			
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bullous erysipelas			
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	7 / 2827 (0.25%)	5 / 2831 (0.18%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			

subjects affected / exposed	10 / 2827 (0.35%)	16 / 2831 (0.57%)
occurrences causally related to treatment / all	0 / 12	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	12 / 2827 (0.42%)	19 / 2831 (0.67%)
occurrences causally related to treatment / all	0 / 13	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	7 / 2827 (0.25%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	7 / 2827 (0.25%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	1 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	2 / 2827 (0.07%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 2827 (0.04%)	7 / 2831 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	17 / 2827 (0.60%)	23 / 2831 (0.81%)
occurrences causally related to treatment / all	0 / 20	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		

subjects affected / exposed	42 / 2827 (1.49%)	12 / 2831 (0.42%)
occurrences causally related to treatment / all	26 / 45	5 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar state		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	2 / 2827 (0.07%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	21 / 2827 (0.74%)	31 / 2831 (1.10%)
occurrences causally related to treatment / all	0 / 23	0 / 33
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia unawareness		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	3 / 2827 (0.11%)	5 / 2831 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		

subjects affected / exposed	8 / 2827 (0.28%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	1 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoproteinaemia		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	3 / 2827 (0.11%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ketoacidosis		
subjects affected / exposed	1 / 2827 (0.04%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	2 / 2827 (0.07%)	3 / 2831 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour lysis syndrome		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calciphylaxis		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic disorder		
subjects affected / exposed	0 / 2827 (0.00%)	1 / 2831 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic complication		

subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	1 / 2827 (0.04%)	0 / 2831 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Decreased appetite		
subjects affected / exposed	0 / 2827 (0.00%)	2 / 2831 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	2 / 2827 (0.07%)	4 / 2831 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	14 / 2827 (0.50%)	22 / 2831 (0.78%)
occurrences causally related to treatment / all	0 / 16	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	12 / 2827 (0.42%)	14 / 2831 (0.49%)
occurrences causally related to treatment / all	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0

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

Non-serious adverse events	Finerenone	Placebo
Total subjects affected by non-serious adverse events		
subjects affected / exposed	1602 / 2827 (56.67%)	1584 / 2831 (55.95%)
Investigations		
Glomerular filtration rate decreased		
subjects affected / exposed	177 / 2827 (6.26%)	130 / 2831 (4.59%)
occurrences (all)	225	146

Vascular disorders Hypertension subjects affected / exposed occurrences (all)	200 / 2827 (7.07%) 229	262 / 2831 (9.25%) 323	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	143 / 2827 (5.06%) 165	147 / 2831 (5.19%) 162	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	201 / 2827 (7.11%) 218	177 / 2831 (6.25%) 196	
General disorders and administration site conditions Oedema peripheral subjects affected / exposed occurrences (all)	183 / 2827 (6.47%) 216	303 / 2831 (10.70%) 359	
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	128 / 2827 (4.53%) 146 183 / 2827 (6.47%) 216	162 / 2831 (5.72%) 179 188 / 2831 (6.64%) 224	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	142 / 2827 (5.02%) 163 175 / 2827 (6.19%) 187	145 / 2831 (5.12%) 157 170 / 2831 (6.00%) 182	
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all)	127 / 2827 (4.49%) 140 241 / 2827 (8.52%) 368	142 / 2831 (5.02%) 188 250 / 2831 (8.83%) 391	

Upper respiratory tract infection subjects affected / exposed occurrences (all)	181 / 2827 (6.40%) 274	185 / 2831 (6.53%) 262	
Urinary tract infection subjects affected / exposed occurrences (all)	168 / 2827 (5.94%) 215	185 / 2831 (6.53%) 259	
Metabolism and nutrition disorders			
Hyperkalaemia subjects affected / exposed occurrences (all)	422 / 2827 (14.93%) 634	212 / 2831 (7.49%) 281	
Hypoglycaemia subjects affected / exposed occurrences (all)	137 / 2827 (4.85%) 212	173 / 2831 (6.11%) 299	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 May 2017	The major modifications specified in Amendment 3 were an increase of study duration and site numbers to account for lower than expected recruitment rate, amended re-screening rules, a modification of an exclusion criterion to allow randomization of subjects with a recent CV disease episode, and the addition of the definition of the endpoint "kidney failure".
26 February 2019	The main modification due to Amendment 4 was to allow performing the post-treatment Visit as a telephone contact, to specify baseline values for subjects who did not immediately start with study drug treatment, to increase the time window after last study drug administration from 3 to 30 days for on-treatment analyses to better reflect the more protracted nature of the development and diagnosis of clinical outcome events of interest in relation to treatment exposure, and to specify the definition of treatment emergent AEs and interruptions of study treatment.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/31655812>

<http://www.ncbi.nlm.nih.gov/pubmed/33264825>

<http://www.ncbi.nlm.nih.gov/pubmed/33198491>