

**Clinical trial results:**

A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase 3 study to investigate efficacy and safety of finerenone on the reduction of cardiovascular morbidity and mortality in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease in addition to standard of care

Summary

EudraCT number	2015-000950-39
Trial protocol	DK SE HU GB AT DE CZ ES FI PT BE BG NL LT PL FR GR RO IE
Global end of trial date	SK IT 02 February 2021

Results information

Result version number	v2 (current)
This version publication date	04 June 2022
First version publication date	10 February 2022
Version creation reason	<ul style="list-style-type: none">• Correction of full data set As per NIH comments.

Trial information**Trial identification**

Sponsor protocol code	BAY94-8862/17530
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02545049
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	02 February 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary objective was to: - Demonstrate whether, in addition to standard of care, finerenone is superior to placebo in delaying the time to first occurrence of cardiovascular (CV) mortality and morbidity in subjects with type 2 diabetes mellitus (T2D) and the clinical diagnosis of diabetic kidney disease (DKD).

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: 95
Country: Number of subjects enrolled	Belgium: 78
Country: Number of subjects enrolled	Bulgaria: 625
Country: Number of subjects enrolled	Switzerland: 26
Country: Number of subjects enrolled	Czechia: 163
Country: Number of subjects enrolled	Germany: 131
Country: Number of subjects enrolled	Denmark: 162
Country: Number of subjects enrolled	Spain: 258
Country: Number of subjects enrolled	Finland: 104
Country: Number of subjects enrolled	France: 47
Country: Number of subjects enrolled	United Kingdom: 67
Country: Number of subjects enrolled	Greece: 29
Country: Number of subjects enrolled	Hungary: 215
Country: Number of subjects enrolled	Ireland: 4
Country: Number of subjects enrolled	Italy: 241

Country: Number of subjects enrolled	Lithuania: 25
Country: Number of subjects enrolled	Netherlands: 74
Country: Number of subjects enrolled	Norway: 38
Country: Number of subjects enrolled	Poland: 145
Country: Number of subjects enrolled	Portugal: 80
Country: Number of subjects enrolled	Romania: 111
Country: Number of subjects enrolled	Russian Federation: 390
Country: Number of subjects enrolled	Slovakia: 37
Country: Number of subjects enrolled	Sweden: 80
Country: Number of subjects enrolled	Turkey: 116
Country: Number of subjects enrolled	Ukraine: 163
Country: Number of subjects enrolled	Canada: 180
Country: Number of subjects enrolled	Puerto Rico: 9
Country: Number of subjects enrolled	United States: 918
Country: Number of subjects enrolled	China: 325
Country: Number of subjects enrolled	Hong Kong: 49
Country: Number of subjects enrolled	Israel: 278
Country: Number of subjects enrolled	Japan: 503
Country: Number of subjects enrolled	Korea, Republic of: 144
Country: Number of subjects enrolled	Malaysia: 64
Country: Number of subjects enrolled	Philippines: 49
Country: Number of subjects enrolled	Singapore: 25
Country: Number of subjects enrolled	Thailand: 40
Country: Number of subjects enrolled	Taiwan: 101
Country: Number of subjects enrolled	Vietnam: 47
Country: Number of subjects enrolled	Argentina: 256
Country: Number of subjects enrolled	Brazil: 210
Country: Number of subjects enrolled	Chile: 72
Country: Number of subjects enrolled	Colombia: 187
Country: Number of subjects enrolled	Mexico: 116
Country: Number of subjects enrolled	Australia: 87
Country: Number of subjects enrolled	New Zealand: 56
Country: Number of subjects enrolled	South Africa: 132
Worldwide total number of subjects	7352
EEA total number of subjects	2742

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)	3510
From 65 to 84 years	3783
85 years and over	59

Subject disposition

Recruitment

Recruitment details:

Study was conducted at multiple centers in 48 countries/regions between 17-Sep-2015 (first subject first visit) and 02-Feb-2021 (last subject last visit).

Pre-assignment

Screening details:

Overall, 19381 subjects were screened. Of them, 11944 subjects were screening failures and 7437 subjects were randomized. 85 subjects were prospectively excluded from the analyses due to critical GCP violations resulting in 7352 in full analysis set. 7341 subjects received study treatment. 1 subject was assigned to placebo but received finerenone.

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	Kerendia
Pharmaceutical forms	Film-coated 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. Study medication was administered 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	Film-coated 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	3686	3666
Treated	3683	3658
Completed	3681	3653
Not completed	5	13
Consent withdrawn by subject	1	7
Lost to follow-up	4	6

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	3686	3666	7352
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	64.13	64.13	-
standard deviation	± 9.67	± 10	-
Sex: Female, Male			
Units: Subjects			
Female	1158	1089	2247
Male	2528	2577	5105
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	73	70	143
Asian	715	739	1454
Native Hawaiian or Other Pacific Islander	17	14	31
Black or African American	113	145	258
White	2672	2605	5277
More than one race	87	86	173
Unknown or Not Reported	9	7	16
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	618	603	1221
Not Hispanic or Latino	3058	3057	6115
Unknown or Not Reported	10	6	16
Urinary albumin-to-creatinine ratio (UACR)			
Units: milligram/gram (mg/g)			
median	302.36	315.06	-
inter-quartile range (Q1-Q3)	105.47 to 749.05	111.24 to 731.01	-
Estimated glomerular filtration rate (eGFR)			
Units: mL/min/1.73m ²			
arithmetic mean	67.62	67.99	-
standard deviation	± 21.65	± 21.74	-

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 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
End point description:	
Number of participants with the first occurrence of the primary cardiovascular (CV) composite outcome, CV death, non-fatal myocardial infarction (MI), non-fatal stroke, or hospitalization for heart failure were reported as descriptive result.	
End point type	Primary
End point timeframe:	
From randomization up until the first occurrence of the CV composite endpoint, or censoring at the end of the study, with an average study duration of 41 months.	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3686	3666		
Units: Subjects				
number (not applicable)	458	519		

Statistical analyses

Statistical analysis title	Primary CV 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	7352
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0264 ^[1]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	0.98

Notes:

[1] - A hierarchical testing procedure was used for the primary and secondary efficacy endpoints with each variable being tested at the adjusted two-sided significance level of 0.04967388.

Secondary: 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
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End point description:

Number of participants with 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 were reported as descriptive result.

End point type	Secondary
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End point timeframe:

From randomization up until the first occurrence of the renal composite endpoint, or censoring at the end of the study, with an average study duration of 41 months

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3686	3666		
Units: Subjects				
number (not applicable)	350	395		

Statistical analyses

Statistical analysis title	Secondary 40% 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
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Number of subjects included in analysis	7352
Analysis specification	Pre-specified
Analysis type	superiority ^[2]
P-value	= 0.0689 ^[3]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.01

Notes:

[2] - If the treatment effect of the 40% renal composite endpoint was not significant, all other endpoints (i.e. all-cause hospitalization, all-cause mortality, change in UACR from baseline to Month 4, and 57% renal composite endpoint) would be tested in an exploratory manner.

[3] - A hierarchical testing procedure was used for the primary and secondary efficacy endpoints with each variable being tested at the adjusted two-sided significance level of 0.04967388.

Secondary: All-cause hospitalization

End point title	All-cause hospitalization
End point description:	
Number of participants with first occurrence of a hospitalization event were reported as descriptive result.	
End point type	Secondary
End point timeframe:	
From randomization up until the first occurrence of the hospitalization due to any cause, or censoring at the end of study, with an average study duration of 41 months	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3686	3666		
Units: Subjects				
number (not applicable)	1573	1605		

Statistical analyses

Statistical analysis title	All-cause hospitalization
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	7352
Analysis specification	Pre-specified
Analysis type	superiority ^[4]
P-value	= 0.3558 ^[5]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.04

Notes:

[4] - If the treatment effect of the 40% renal composite endpoint was not significant, all other endpoints (i.e. all-cause hospitalization, all-cause mortality, change in UACR from baseline to Month 4, and 57% renal composite endpoint) would be tested in an exploratory manner.

[5] - A hierarchical testing procedure was used for the primary and secondary efficacy endpoints with each variable being tested at the adjusted two-sided significance level of 0.04967388.

Secondary: All-cause mortality

End point title	All-cause mortality
End point description:	
Number of participants with death due to any cause were reported as descriptive result. Number of participants with outcome death reported here includes deaths occurred after randomization until the end of the study visit. Deaths after end of study visit are not included in this table.	
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 study duration of 41 months	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3686	3666		
Units: Subjects				
number (not applicable)	333	370		

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	7352
Analysis specification	Pre-specified
Analysis type	superiority ^[6]
P-value	= 0.1337 ^[7]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.04

Notes:

[6] - If the treatment effect of the 40% renal composite endpoint was not significant, all other endpoints (i.e. all-cause hospitalization, all-cause mortality, change in UACR from baseline to Month 4, and 57% renal composite endpoint) would be tested in an exploratory manner.

[7] - A hierarchical testing procedure was used for the primary and secondary efficacy endpoints with each variable being tested at the adjusted two-sided significance level of 0.04967388.

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 participant was excluded from this analysis. Ratio of UACR at Month 4 to UACR at baseline is reported as the change.

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	3521	3476		
Units: Ratio				
least squares mean (confidence interval 95%)	0.624 (0.606 to 0.642)	0.922 (0.896 to 0.949)		

Statistical analyses

Statistical analysis title	Change in UACR from baseline to Month 4
Comparison groups	Finerenone v Placebo

Number of subjects included in analysis	6997
Analysis specification	Pre-specified
Analysis type	superiority ^[8]
P-value	< 0.0001 ^[9]
Method	ANCOVA
Parameter estimate	Ratio of least squares means
Point estimate	0.676
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.704

Notes:

[8] - If the treatment effect of the 40% renal composite endpoint was not significant, all other endpoints (i.e. all-cause hospitalization, all-cause mortality, change in UACR from baseline to Month 4, and 57% renal composite endpoint) would be tested in an exploratory manner.

[9] - P-value from F-test of equal means between the treatment groups. A hierarchical testing procedure was used for the primary and secondary efficacy endpoints with each variable being tested at the adjusted two-sided significance level of 0.04967388.

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:

Number of participants with first occurrence of the 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 reported as descriptive result.

End point type	Secondary
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End point timeframe:

From randomization up until the first occurrence of the renal composite endpoint, or censoring at the end of the study, with an average study duration of 41 months

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3686	3666		
Units: Subjects				
number (not applicable)	108	139		

Statistical analyses

Statistical analysis title	Secondary 57% 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
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Number of subjects included in analysis	7352
Analysis specification	Pre-specified
Analysis type	superiority ^[10]
P-value	= 0.0406 ^[11]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.99

Notes:

[10] - If the treatment effect of the 40% renal composite endpoint was not significant, all other endpoints (i.e. all-cause hospitalization, all-cause mortality, change in UACR from baseline to Month 4, and 57% renal composite endpoint) would be tested in an exploratory manner

[11] - A hierarchical testing procedure was used for the primary and secondary efficacy endpoints with each variable being tested at the adjusted two-sided significance level of 0.04967388.

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 36 months

Adverse event reporting additional description:

Adverse events (AEs) are reported for the safety analysis set (SAF) that comprised all randomized subjects who took at least 1 dose of study drug (except those with critical GCP violations). AEs for all-cause mortality are reported for the FAS and considers all deaths after randomization, including those after the end of study visit.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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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	1158 / 3683 (31.44%)	1215 / 3658 (33.21%)	
number of deaths (all causes)	339	383	
number of deaths resulting from adverse events	79	100	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma			
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			

subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Basal cell carcinoma		
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of prostate		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	11 / 3683 (0.30%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 13	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		

subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	3 / 3683 (0.08%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bone cancer		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	1 / 3683 (0.03%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Cervix carcinoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Chronic lymphocytic leukaemia		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Colon cancer		
subjects affected / exposed	14 / 3683 (0.38%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	1 / 15	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 1
Enchondromatosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric cancer		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemangioblastoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypergammaglobulinaemia benign monoclonal		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypopharyngeal cancer		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1
Laryngeal squamous cell carcinoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant pleural effusion		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lung		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to liver		
subjects affected / exposed	3 / 3683 (0.08%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myelodysplastic syndrome		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm prostate		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm skin		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Oropharyngeal squamous cell carcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	5 / 3683 (0.14%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 5	1 / 5
deaths causally related to treatment / all	0 / 1	0 / 3
Pancreatic carcinoma metastatic		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Papillary thyroid cancer		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Papilloma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	4 / 3683 (0.11%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer recurrent		

subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory papilloma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sarcoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Seminoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin papilloma		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Squamous cell carcinoma		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 the oral cavity		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thymoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid adenoma		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	3 / 3683 (0.08%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine cancer		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour ulceration		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		

subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Salivary gland adenoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal cancer metastatic		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ear neoplasm malignant		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal neoplasm		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Choroid neoplasm		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Testis cancer		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	7 / 3683 (0.19%)	8 / 3658 (0.22%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 4
Metastases to central nervous system		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatic carcinoma stage IV		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer		
subjects affected / exposed	10 / 3683 (0.27%)	24 / 3658 (0.66%)
occurrences causally related to treatment / all	0 / 10	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Benign anorectal neoplasm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastrointestinal neoplasm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon neoplasm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Female reproductive neoplasm		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal cancer		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian neoplasm		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal neoplasm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal neoplasm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Lung neoplasm		
subjects affected / exposed	1 / 3683 (0.03%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
Rectal neoplasm		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastasis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour invasion		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		

subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangioma of spleen		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epithelioid mesothelioma		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic cancer		
subjects affected / exposed	5 / 3683 (0.14%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 3
Hepatocellular carcinoma		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 2
Invasive lobular breast carcinoma		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive papillary breast carcinoma		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Triple negative breast cancer			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma recurrent			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary renal cell carcinoma			
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the parotid gland			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Aortic aneurysm			
subjects affected / exposed	4 / 3683 (0.11%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	5 / 3683 (0.14%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortitis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
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	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giant cell arteritis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	12 / 3683 (0.33%)	22 / 3658 (0.60%)
occurrences causally related to treatment / all	0 / 12	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	2 / 3683 (0.05%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	1 / 3683 (0.03%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Subclavian steal syndrome		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic hypertension		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vasculitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post thrombotic syndrome		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Labile hypertension		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	3 / 3683 (0.08%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive urgency		
subjects affected / exposed	1 / 3683 (0.03%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		

subjects affected / exposed	4 / 3683 (0.11%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	2 / 3683 (0.05%)	6 / 3658 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery occlusion			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
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	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm rupture			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abscess drainage			

subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm repair		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve replacement		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicectomy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula operation		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder calculus removal		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neck resection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac pacemaker insertion		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid endarterectomy		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	2 / 3683 (0.05%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Circumcision		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery bypass		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Finger amputation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hip arthroplasty		
subjects affected / exposed	4 / 3683 (0.11%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hysterectomy		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia repair		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia repair		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intensive care		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Insertion of ambulatory peritoneal catheter		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Internal fixation of fracture		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Knee arthroplasty		
subjects affected / exposed	8 / 3683 (0.22%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Leg amputation		
subjects affected / exposed	3 / 3683 (0.08%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma excision		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung lobectomy		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal polypectomy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroidectomy		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotidectomy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radical hysterectomy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radioactive iodine therapy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Removal of foreign body from larynx		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Removal of internal fixation		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst excision		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal stone removal		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scar excision		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Roux loop conversion		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer excision		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal laminectomy		
subjects affected / exposed	3 / 3683 (0.08%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal decompression		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.11%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia repair		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polypectomy			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitrectomy			
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder arthroplasty			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary revascularisation			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral stent insertion			

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radical prostatectomy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus management		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Preoperative care		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transurethral bladder resection		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neurolysis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Caecum operation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery angioplasty		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral nerve decompression		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin neoplasm excision		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctocolectomy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ablation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brachytherapy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb operation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic surgery		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone operation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chemotherapy		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colectomy		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye operation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid operation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrectomy		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric bypass		

subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocele operation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lithotripsy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal operation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroidectomy		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth extraction		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein operation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin graft		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug therapy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent insertion		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract operation		
subjects affected / exposed	7 / 3683 (0.19%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele repair		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Percutaneous coronary intervention		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraocular lens implant		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosurgery		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic stent placement		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery bypass		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal polypectomy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast conserving surgery		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transcatheter aortic valve implantation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial appendage closure		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic surgery		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cheilectomy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary catheter removal		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal disorder prophylaxis			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug delivery device placement			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular stem cell transplant			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	18 / 3683 (0.49%)	20 / 3658 (0.55%)	
occurrences causally related to treatment / all	0 / 18	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	8 / 3683 (0.22%)	6 / 3658 (0.16%)	
occurrences causally related to treatment / all	0 / 8	1 / 6	
deaths causally related to treatment / all	0 / 8	1 / 6	
Generalised oedema			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	1 / 3683 (0.03%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 1	1 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	6 / 3683 (0.16%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden death		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral swelling		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		

subjects affected / exposed	2 / 3683 (0.05%)	8 / 3658 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 2
Oedema due to cardiac disease		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhagic cyst		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adhesion		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyp		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug intolerance		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Complication associated with device		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hanging			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	12 / 3683 (0.33%)	10 / 3658 (0.27%)	
occurrences causally related to treatment / all	0 / 12	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast necrosis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Endometrial hyperplasia			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	1 / 3683 (0.03%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Prostatic disorder			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatism			
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile dysfunction			

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal dermatitis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 3683 (0.03%)	4 / 3658 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	12 / 3683 (0.33%)	9 / 3658 (0.25%)	
occurrences causally related to treatment / all	0 / 12	0 / 10	
deaths causally related to treatment / all	0 / 2	0 / 4	
Asphyxia			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aspiration			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			
subjects affected / exposed	4 / 3683 (0.11%)	5 / 3658 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchitis chronic			

subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	22 / 3683 (0.60%)	16 / 3658 (0.44%)
occurrences causally related to treatment / all	0 / 24	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic respiratory failure		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphonia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	9 / 3683 (0.24%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		

subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiccups		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercapnia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal oedema		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	5 / 3683 (0.14%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia aspiration		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary congestion		
subjects affected / exposed	0 / 3683 (0.00%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary embolism		
subjects affected / exposed	6 / 3683 (0.16%)	11 / 3658 (0.30%)
occurrences causally related to treatment / all	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 2
Pulmonary hypertension		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary infarction		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	2 / 3683 (0.05%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory acidosis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory disorder		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		
subjects affected / exposed	6 / 3683 (0.16%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 2
Sleep apnoea syndrome		
subjects affected / exposed	5 / 3683 (0.14%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal mass		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	4 / 3683 (0.11%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal disorder		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asthmatic crisis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial hyperreactivity		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic hydrothorax		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alveolar lung disease		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung perforation		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small airways disease			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Confusional state			
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delusional disorder, unspecified type			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug abuse			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			

subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder due to a general medical condition			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide threat			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device malfunction			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	5 / 3683 (0.14%)	3 / 3658 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

Biliary colic			
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary fistula			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	7 / 3683 (0.19%)	5 / 3658 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	9 / 3683 (0.24%)	7 / 3658 (0.19%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	5 / 3683 (0.14%)	7 / 3658 (0.19%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatitis			

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cirrhosis alcoholic		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fatty liver alcoholic		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic failure		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic function abnormal		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatorenal syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Jaundice		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Liver disorder		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Portal hypertension		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Portal vein thrombosis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystocholangitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder polyp		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-alcoholic steatohepatitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary dyskinesia		

subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary biliary cholangitis			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Arthroscopy			
subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy bladder			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy liver			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy prostate			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
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	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Blood magnesium decreased		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium decreased		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (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	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colonoscopy		
subjects affected / exposed	4 / 3683 (0.11%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colonoscopy normal		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Computerised tomogram		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram abnormal		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endoscopy		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerular filtration rate decreased		
subjects affected / exposed	4 / 3683 (0.11%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glycosylated haemoglobin increased		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematocrit decreased		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urine present		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angiogram cerebral		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep study		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure orthostatic decreased		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin increased		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac function test abnormal		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anticoagulation drug level below therapeutic		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angiogram		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Investigation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 test positive		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	0 / 3683 (0.00%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Endobronchial ultrasound		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stoma output increased		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cancer staging		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiocardiogram			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test negative			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			

subjects affected / exposed	6 / 3683 (0.16%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage injury		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis radiation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	4 / 3683 (0.11%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Femoral neck fracture		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		

subjects affected / exposed	8 / 3683 (0.22%)	8 / 3658 (0.22%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
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 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body aspiration		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gun shot wound		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	5 / 3683 (0.14%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		

subjects affected / exposed	0 / 3683 (0.00%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Injury corneal		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Multiple injuries		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Overdose		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation proctitis		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	2 / 3683 (0.05%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Scapula fracture		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic injury		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	3 / 3683 (0.08%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	5 / 3683 (0.14%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic ulcer		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular injury		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia postoperative		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic fracture		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	4 / 3683 (0.11%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Intervertebral disc injury		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac procedure complication		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Procedural complication		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal injury		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pelvic fracture		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Skin injury		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stomal hernia		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular anastomosis aneurysm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral hyperperfusion syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin abrasion		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone contusion		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Heat illness		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound contamination		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cranio-cerebral injury		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Procedural haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin wound		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	4 / 3683 (0.11%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eye contusion		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural intestinal perforation		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative delirium			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental restoration failure			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular procedural complication			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive tract procedural complication			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arnold-Chiari malformation			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypospadias			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenomatous polyposis coli			

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anomaly of middle ear congenital			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)	
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	4 / 3683 (0.11%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	3 / 3683 (0.08%)	3 / 3658 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	4 / 3683 (0.11%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Atrial fibrillation		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		

subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac failure		
subjects affected / exposed	5 / 3683 (0.14%)	10 / 3658 (0.27%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		
subjects affected / exposed	4 / 3683 (0.11%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac failure chronic		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale chronic		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	5 / 3683 (0.14%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	3 / 3683 (0.08%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		

subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial block		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachycardia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular hypertrophy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ventricular hypokinesia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Acute coronary syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve disease		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute left ventricular failure		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachyarrhythmia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Paroxysmal atrioventricular block		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac dysfunction		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem haemorrhage			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carotid artery stenosis			
subjects affected / exposed	3 / 3683 (0.08%)	4 / 3658 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrospinal fluid leakage		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic hyperosmolar coma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidotic hyperglycaemic coma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic neuropathy		
subjects affected / exposed	11 / 3683 (0.30%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	7 / 3683 (0.19%)	8 / 3658 (0.22%)
occurrences causally related to treatment / all	0 / 10	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyskinesia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
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	4 / 3683 (0.11%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		

subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraventricular haemorrhage		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lethargy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meralgia paraesthetica		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Moyamoya disease		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		

subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	3 / 3683 (0.08%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		

subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sensory disturbance		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Somnolence		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Syncope		
subjects affected / exposed	14 / 3683 (0.38%)	16 / 3658 (0.44%)
occurrences causally related to treatment / all	0 / 14	1 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Tension headache		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ulnar neuritis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular headache		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo CNS origin		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Balance disorder		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysstasia		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar infarction		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial nerve disorder		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mononeuropathy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Amputation stump pain		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic unconsciousness		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral nerve paresis		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posthaemorrhagic hydrocephalus			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system vasculitis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	18 / 3683 (0.49%)	15 / 3658 (0.41%)	
occurrences causally related to treatment / all	0 / 21	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hilar lymphadenopathy			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocoagulable state			

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypereosinophilic syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acquired haemophilia		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicytopenia			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
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	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	7 / 3683 (0.19%)	6 / 3658 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular ataxia			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			

subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute vestibular syndrome			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	15 / 3683 (0.41%)	11 / 3658 (0.30%)	
occurrences causally related to treatment / all	0 / 18	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatochalasis			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic eye disease			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			

subjects affected / exposed	11 / 3683 (0.30%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	0 / 21	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extraocular muscle paresis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	4 / 3683 (0.11%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmoplegia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		

subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy proliferative		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vision blurred		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vitreous haemorrhage		
subjects affected / exposed	16 / 3683 (0.43%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	1 / 23	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Macular hole		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid cyst		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Age-related macular degeneration		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhegmatogenous retinal detachment			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular ischaemic syndrome			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal mass			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	5 / 3683 (0.14%)	6 / 3658 (0.16%)	
occurrences causally related to treatment / all	1 / 5	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abdominal pain lower			

subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	7 / 3683 (0.19%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 8	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.08%)	2 / 3658 (0.05%)
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 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Dyspepsia		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		

subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroesophageal reflux disease		
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	7 / 3683 (0.19%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal pain		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	4 / 3683 (0.11%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	2 / 3683 (0.05%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intestinal obstruction		
subjects affected / exposed	1 / 3683 (0.03%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
Melaena		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric vein thrombosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mouth haemorrhage		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal haemorrhage		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal obstruction		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	5 / 3683 (0.14%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		

subjects affected / exposed	12 / 3683 (0.33%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 16	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis necrotising		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis relapsing		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotid gland enlargement		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	3 / 3683 (0.08%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal perforation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Swollen tongue		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	4 / 3683 (0.11%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Volvulus		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		
subjects affected / exposed	5 / 3683 (0.14%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic mass		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal discharge		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric dysplasia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal dysplasia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical ileus		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		

subjects affected / exposed	14 / 3683 (0.38%)	11 / 3658 (0.30%)
occurrences causally related to treatment / all	0 / 16	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal polyp		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Internal hernia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous pancreatitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal haemorrhage		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric varices haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal oedema		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal mass		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal symptom		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric mucosal lesion		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland disorder		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal inflammation		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic duct stenosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Abdominal wall haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Omental infarction		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Functional gastrointestinal disorder		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia perforation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Dental cyst		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hidradenitis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ingrowing nail			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palmoplantar keratoderma			

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigoid		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	12 / 3683 (0.33%)	15 / 3658 (0.41%)
occurrences causally related to treatment / all	0 / 12	0 / 20
deaths causally related to treatment / all	0 / 1	0 / 0
Neuropathic ulcer		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ulcer		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrobiosis lipoidica diabetorum		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic skin eruption		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	23 / 3683 (0.62%)	18 / 3658 (0.49%)	
occurrences causally related to treatment / all	0 / 24	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiokeratoma			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reactive perforating collagenosis			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic cheiroarthropathy			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Albuminuria			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	3 / 3683 (0.08%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			

subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis chronic		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis membranous		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	5 / 3683 (0.14%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	12 / 3683 (0.33%)	8 / 3658 (0.22%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		

subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	4 / 3683 (0.11%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	2 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary hesitation		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric obstruction		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (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	5 / 3683 (0.14%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Vesicoureteric reflux		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract disorder		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neck sclerosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract obstruction		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	10 / 3683 (0.27%)	26 / 3658 (0.71%)
occurrences causally related to treatment / all	0 / 12	0 / 38
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		

subjects affected / exposed	2 / 3683 (0.05%)	6 / 3658 (0.16%)	
occurrences causally related to treatment / all	0 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	38 / 3683 (1.03%)	46 / 3658 (1.26%)	
occurrences causally related to treatment / all	9 / 39	3 / 48	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower urinary tract symptoms			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	6 / 3683 (0.16%)	5 / 3658 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subacute kidney injury			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			

subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary hyperaldosteronism			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	6 / 3683 (0.16%)	6 / 3658 (0.16%)	
occurrences causally related to treatment / all	1 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropathy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	8 / 3683 (0.22%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondromalacia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fasciitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Groin pain		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	3 / 3683 (0.08%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		

subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myositis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	0 / 3683 (0.00%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic arthropathy		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	22 / 3683 (0.60%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 23	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Osteolysis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plantar fascial fibromatosis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Resorption bone increased		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	8 / 3683 (0.22%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Spondyloarthropathy		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue haemorrhage		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal discomfort		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc compression		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facet joint syndrome		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis stenosaurs		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal ligament ossification		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		

subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inclusion body myositis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral foraminal stenosis		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	0 / 3683 (0.00%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diastasis recti abdominis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon discomfort		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral lateral recess stenosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal stenosis		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Immobilisation syndrome		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal cellulitis			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	5 / 3683 (0.14%)	5 / 3658 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerotic gangrene			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspergilloma			
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	7 / 3683 (0.19%)	9 / 3658 (0.25%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	40 / 3683 (1.09%)	28 / 3658 (0.77%)
occurrences causally related to treatment / all	0 / 46	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 1
Cellulitis gangrenous		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis C		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal abscess		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	4 / 3683 (0.11%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	10 / 3683 (0.27%)	15 / 3658 (0.41%)
occurrences causally related to treatment / all	0 / 12	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fournier's gangrene		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Furuncle		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	5 / 3683 (0.14%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		

subjects affected / exposed	11 / 3683 (0.30%)	15 / 3658 (0.41%)
occurrences causally related to treatment / all	0 / 12	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis rotavirus		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	3 / 3683 (0.08%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HIV infection		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 3683 (0.03%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious mononucleosis		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective myositis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	5 / 3683 (0.14%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Labyrinthitis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	9 / 3683 (0.24%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	1 / 3683 (0.03%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		

subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	12 / 3683 (0.33%)	13 / 3658 (0.36%)
occurrences causally related to treatment / all	0 / 16	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	3 / 3683 (0.08%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paronychia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic inflammatory disease		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pilonidal cyst		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	73 / 3683 (1.98%)	113 / 3658 (3.09%)
occurrences causally related to treatment / all	0 / 77	1 / 121
deaths causally related to treatment / all	0 / 4	0 / 7
Pneumonia haemophilus		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia klebsiella		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	2 / 3683 (0.05%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	7 / 3683 (0.19%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic abscess		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mycosis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Pyelitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	9 / 3683 (0.24%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	4 / 3683 (0.11%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Salpingitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	16 / 3683 (0.43%)	20 / 3658 (0.55%)
occurrences causally related to treatment / all	1 / 16	0 / 21
deaths causally related to treatment / all	0 / 1	0 / 4
Septic shock		
subjects affected / exposed	4 / 3683 (0.11%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Sialoadenitis		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	0 / 3683 (0.00%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Subacute endocarditis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	4 / 3683 (0.11%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	4 / 3683 (0.11%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		

subjects affected / exposed	28 / 3683 (0.76%)	39 / 3658 (1.07%)
occurrences causally related to treatment / all	0 / 33	0 / 40
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular neuronitis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	12 / 3683 (0.33%)	13 / 3658 (0.36%)
occurrences causally related to treatment / all	0 / 15	0 / 13
deaths causally related to treatment / all	0 / 2	0 / 0
Tooth infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	2 / 3683 (0.05%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinobronchitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection fungal		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess limb		
subjects affected / exposed	9 / 3683 (0.24%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess soft tissue		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis viral		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronavirus infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile infection		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		

subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
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	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess neck		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stenotrophomonas sepsis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal infection		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Catheter site infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital cellulitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective tenosynovitis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal sepsis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute hepatitis B		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intervertebral discitis		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	7 / 3683 (0.19%)	5 / 3658 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial infection		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	2 / 3683 (0.05%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Genitourinary tract infection		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis viral		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis bacterial		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	1 / 3683 (0.03%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	6 / 3683 (0.16%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa bacterial		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis bacterial		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis bacterial		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lymphadenitis bacterial		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection bacterial		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysematous pyelonephritis		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal viral infection		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster meningoencephalitis		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site infection		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal sepsis		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord abscess		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising soft tissue infection		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bite		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular device infection		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft infection			
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	17 / 3683 (0.46%)	22 / 3658 (0.60%)	
occurrences causally related to treatment / all	0 / 17	0 / 22	
deaths causally related to treatment / all	0 / 5	0 / 9	
COVID-19 pneumonia			
subjects affected / exposed	9 / 3683 (0.24%)	11 / 3658 (0.30%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 2	0 / 1	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	8 / 3683 (0.22%)	10 / 3658 (0.27%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	20 / 3683 (0.54%)	25 / 3658 (0.68%)	
occurrences causally related to treatment / all	0 / 24	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			

subjects affected / exposed	27 / 3683 (0.73%)	17 / 3658 (0.46%)
occurrences causally related to treatment / all	0 / 34	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	3 / 3683 (0.08%)	8 / 3658 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	0 / 3683 (0.00%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	2 / 3683 (0.05%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	3 / 3683 (0.08%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	23 / 3683 (0.62%)	11 / 3658 (0.30%)
occurrences causally related to treatment / all	0 / 24	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	23 / 3683 (0.62%)	4 / 3658 (0.11%)
occurrences causally related to treatment / all	15 / 25	4 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		

subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	17 / 3683 (0.46%)	28 / 3658 (0.77%)
occurrences causally related to treatment / all	0 / 20	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	0 / 3683 (0.00%)	6 / 3658 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	6 / 3683 (0.16%)	7 / 3658 (0.19%)
occurrences causally related to treatment / all	2 / 7	3 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 3683 (0.05%)	0 / 3658 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	1 / 3683 (0.03%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	4 / 3683 (0.11%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic syndrome		

subjects affected / exposed	1 / 3683 (0.03%)	0 / 3658 (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 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic complication		
subjects affected / exposed	1 / 3683 (0.03%)	2 / 3658 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mineral metabolism disorder		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	2 / 3683 (0.05%)	3 / 3658 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis calcarea		
subjects affected / exposed	0 / 3683 (0.00%)	1 / 3658 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	33 / 3683 (0.90%)	25 / 3658 (0.68%)
occurrences causally related to treatment / all	0 / 45	0 / 33
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	18 / 3683 (0.49%)	13 / 3658 (0.36%)
occurrences causally related to treatment / all	0 / 20	0 / 16
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	1797 / 3683 (48.79%)	1717 / 3658 (46.94%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	199 / 3683 (5.40%)	296 / 3658 (8.09%)	
occurrences (all)	241	347	
Nervous system disorders			
Dizziness			
subjects affected / exposed	190 / 3683 (5.16%)	166 / 3658 (4.54%)	
occurrences (all)	218	184	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	210 / 3683 (5.70%)	199 / 3658 (5.44%)	
occurrences (all)	227	215	
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	197 / 3683 (5.35%)	278 / 3658 (7.60%)	
occurrences (all)	227	343	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	185 / 3683 (5.02%)	171 / 3658 (4.67%)	
occurrences (all)	213	192	
Diarrhoea			
subjects affected / exposed	235 / 3683 (6.38%)	220 / 3658 (6.01%)	
occurrences (all)	283	271	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	296 / 3683 (8.04%)	260 / 3658 (7.11%)	
occurrences (all)	379	337	
Back pain			
subjects affected / exposed	260 / 3683 (7.06%)	252 / 3658 (6.89%)	
occurrences (all)	288	287	
Infections and infestations			

Bronchitis			
subjects affected / exposed	191 / 3683 (5.19%)	176 / 3658 (4.81%)	
occurrences (all)	238	214	
Upper respiratory tract infection			
subjects affected / exposed	225 / 3683 (6.11%)	203 / 3658 (5.55%)	
occurrences (all)	351	310	
Nasopharyngitis			
subjects affected / exposed	318 / 3683 (8.63%)	327 / 3658 (8.94%)	
occurrences (all)	537	497	
Urinary tract infection			
subjects affected / exposed	246 / 3683 (6.68%)	220 / 3658 (6.01%)	
occurrences (all)	335	313	
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	322 / 3683 (8.74%)	159 / 3658 (4.35%)	
occurrences (all)	470	219	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 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".
12 March 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

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

None.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/31665733>

<http://www.ncbi.nlm.nih.gov/pubmed/34449181>