

**Clinical trial results:****A RANDOMIZED, PLACEBO CONTROLLED CLINICAL TRIAL TO EVALUATE CARDIOVASCULAR OUTCOMES AFTER TREATMENT WITH EXENATIDE ONCE WEEKLY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS****Summary**

EudraCT number	2010-021069-63
Trial protocol	DE LT LV AT GB CZ SK HU BG IT BE NL ES
Global end of trial date	24 April 2017

Results information

Result version number	v1 (current)
This version publication date	23 May 2018
First version publication date	23 May 2018

Trial information**Trial identification**

Sponsor protocol code	D5551C00003
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca Inc.
Sponsor organisation address	950 Wind River Ln, Gaithersburg, United States, MD, 20878
Public contact	Peter Ohman, AstraZeneca Inc., 1 (301)398-0120, Peter.Ohman@astrazeneca.com
Scientific contact	Peter Ohman, AstraZeneca Inc., 1 (301)398-0120, Peter.Ohman@astrazeneca.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 March 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 April 2017
Global end of trial reached?	Yes
Global end of trial date	24 April 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the impact of including EQW in addition to usual care vs. usual care without EQW on major CV outcomes as measured by the primary CV composite endpoint of CV-related death, nonfatal myocardial infarction (MI), or nonfatal stroke.

Protection of trial subjects:

Treated with routine care.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 June 2010
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: 278
Country: Number of subjects enrolled	Belgium: 28
Country: Number of subjects enrolled	Bulgaria: 378
Country: Number of subjects enrolled	Czech Republic: 138
Country: Number of subjects enrolled	Germany: 982
Country: Number of subjects enrolled	Hungary: 1047
Country: Number of subjects enrolled	Israel: 441
Country: Number of subjects enrolled	Italy: 82
Country: Number of subjects enrolled	Latvia: 228
Country: Number of subjects enrolled	Lithuania: 240
Country: Number of subjects enrolled	Netherlands: 89
Country: Number of subjects enrolled	Poland: 412
Country: Number of subjects enrolled	Romania: 362
Country: Number of subjects enrolled	Russian Federation: 207
Country: Number of subjects enrolled	Slovakia: 397
Country: Number of subjects enrolled	South Africa: 306
Country: Number of subjects enrolled	Spain: 220
Country: Number of subjects enrolled	Ukraine: 606
Country: Number of subjects enrolled	United Kingdom: 347
Country: Number of subjects enrolled	Canada: 544
Country: Number of subjects enrolled	United States: 3164

Country: Number of subjects enrolled	Argentina: 189
Country: Number of subjects enrolled	Brazil: 1728
Country: Number of subjects enrolled	Chile: 134
Country: Number of subjects enrolled	Colombia: 275
Country: Number of subjects enrolled	Mexico: 401
Country: Number of subjects enrolled	Australia: 186
Country: Number of subjects enrolled	China: 300
Country: Number of subjects enrolled	Hong Kong: 158
Country: Number of subjects enrolled	Malaysia: 124
Country: Number of subjects enrolled	New Zealand: 151
Country: Number of subjects enrolled	Philippines: 254
Country: Number of subjects enrolled	Korea, Republic of: 215
Country: Number of subjects enrolled	Taiwan: 122
Country: Number of subjects enrolled	Thailand: 19
Worldwide total number of subjects	14752
EEA total number of subjects	5228

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)	8813
From 65 to 84 years	5888
85 years and over	51

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Informed consent, and if feasible, randomization will occur at the initial trial visit for patients satisfying all inclusion and exclusion criteria. 15185 pts were enrolled at screening/randomization visit and 433 failed screening criteria.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Exenatide once weekly

Arm description:

Exenatide 2mg once weekly subcutaneous injections

Arm type	Experimental
Investigational medicinal product name	Exenatide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

2 mg one time per week, injection

Arm title	Placebo
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Arm description:

Matching placebo subcutaneous injections

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

one time per week, injection

Number of subjects in period 1	Exenatide once weekly	Placebo
Started	7356	7396
Completed	7094	7093
Not completed	262	303
Consent withdrawn by subject	223	270
Lost to follow-up	39	33

Baseline characteristics

Reporting groups

Reporting group title	Exenatide once weekly
Reporting group description: Exenatide 2mg once weekly subcutaneous injections	
Reporting group title	Placebo
Reporting group description: Matching placebo subcutaneous injections	

Reporting group values	Exenatide once weekly	Placebo	Total
Number of subjects	7356	7396	14752
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4392	4421	8813
From 65-84 years	2939	2949	5888
85 years and over	25	26	51
Age Continuous			
Age at enrollment Units: Years			
arithmetic mean	61.8	61.9	
standard deviation	± 9.4	± 9.4	-
Sex: Female, Male Units: Subjects			
MALE	4562	4587	9149
FEMALE	2794	2809	5603
Race/Ethnicity, Customized Units: Subjects			
WHITE	5554	5621	11175
BLACK OR AFRICAN AMERICAN	442	436	878
ASIAN	725	727	1452
INDIAN (AMERICAN) OR ALASKA NATIVE	38	35	73
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	18	17	35
HISPANIC	577	557	1134
MISSING	2	3	5
Region of Enrollment Units: Subjects			
ASIA PACIFIC	769	760	1529
EUROPE	3389	3399	6788
LATIN AMERICA	1364	1363	2727

NORTH AMERICA	1834	1874	3708
Prior CV Event			
Patient had prior cardiovascular event or not at randomization			
Units: Subjects			
Has Prior CV Event	5394	5388	10782
No Prior CV Event	1962	2008	3970

End points

End points reporting groups

Reporting group title	Exenatide once weekly
Reporting group description:	Exenatide 2mg once weekly subcutaneous injections
Reporting group title	Placebo
Reporting group description:	Matching placebo subcutaneous injections

Primary: Primary Efficacy Outcome MACE Events

End point title	Primary Efficacy Outcome MACE Events
End point description:	The primary efficacy outcome variable is defined as the composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke
End point type	Primary
End point timeframe:	Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Number of patients who had a MACE event	839	905		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo
Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.061
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.832
upper limit	1.004

Primary: Primary Safety Outcome MACE Events

End point title	Primary Safety Outcome MACE Events
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End point description:

The primary safety outcome variable is defined as the composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke

End point type	Primary
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End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Number of patients who had a MACE event	839	905		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo
Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.832
upper limit	1.004

Secondary: Secondary Efficacy Outcome All-Cause Mortality

End point title	Secondary Efficacy Outcome All-Cause Mortality
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End point description:

The secondary efficacy outcome variable is defined as the all-cause mortality (deaths).

End point type	Secondary
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End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Number of patients who died	507	584		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo
Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.016
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.97

Secondary: Secondary Efficacy Outcome CV Death

End point title	Secondary Efficacy Outcome CV Death
End point description:	Component of the primary efficacy outcome: cardiovascular death.
End point type	Secondary
End point timeframe:	Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Number of patients who had CV death	340	383		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo
Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.096
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.02

Secondary: Secondary Efficacy Outcome MI

End point title	Secondary Efficacy Outcome MI
End point description:	
Component of primary efficacy outcome: fatal or non-fatal MI.	
End point type	Secondary
End point timeframe:	
Time to first event. Information collected during study period (anticipated to be up to 7.5 years).	

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Number of patients who had an MI event	483	493		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo

Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.622
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.1

Secondary: Secondary Efficacy Outcome Stroke

End point title	Secondary Efficacy Outcome Stroke
End point description:	
Component of primary efficacy outcome: fatal or non-fatal stroke.	
End point type	Secondary
End point timeframe:	
Time to first event. Information collected during study period (anticipated to be up to 7.5 years).	

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Number of patients who had stroke	187	218		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo
Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.095
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.03

Secondary: Secondary Efficacy Outcome Hospitalization for ACS

End point title	Secondary Efficacy Outcome Hospitalization for ACS
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End point description:

The secondary efficacy outcome variable is defined as hospitalization for acute coronary syndrome.

End point type	Secondary
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End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Num of pts with hospitalization due to ACS	602	570		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo
Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.402
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.18

Secondary: Secondary Efficacy Outcome Hospitalization for HF

End point title	Secondary Efficacy Outcome Hospitalization for HF
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End point description:

The secondary efficacy outcome variable is defined as hospitalization for heart failure.

End point type	Secondary
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End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

End point values	Exenatide once weekly	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7356	7396		
Units: Participants				
Number of patients who were hospitalization for HF	219	231		

Statistical analyses

Statistical analysis title	Cox Regression
Comparison groups	Exenatide once weekly v Placebo
Number of subjects included in analysis	14752
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.485
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.13

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From first dose of study drug until last study visit

Adverse event reporting additional description:

Only serious adverse event is collected for this study.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	EQW 2 mg
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Only SAE are collected in this study.

Serious adverse events	Placebo	EQW 2 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	1222 / 7372 (16.58%)	1234 / 7344 (16.80%)	
number of deaths (all causes)	584	507	
number of deaths resulting from adverse events	87	70	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACTH-producing pituitary tumour			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	4 / 7372 (0.05%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Adenocarcinoma			
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Adenocarcinoma gastric			

subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of appendix		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	9 / 7372 (0.12%)	12 / 7344 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 1
Adenoma benign		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Angiosarcoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix cancer		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	3 / 7372 (0.04%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	25 / 7372 (0.34%)	25 / 7344 (0.34%)
occurrences causally related to treatment / all	0 / 33	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign laryngeal neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign oesophageal neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign ovarian tumour		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign small intestinal neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct cancer		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	7 / 7372 (0.09%)	9 / 7344 (0.12%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage 0, with cancer in situ		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder papilloma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	5 / 7372 (0.07%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone cancer		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's disease		
subjects affected / exposed	2 / 7372 (0.03%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm malignant		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Breast cancer		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer female		
subjects affected / exposed	14 / 7372 (0.19%)	16 / 7344 (0.22%)
occurrences causally related to treatment / all	1 / 14	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 2
Breast cancer male		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Breast neoplasm		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	3 / 7372 (0.04%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cancer pain		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid body tumour		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemangioma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma recurrent		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Choroid melanoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	3 / 7372 (0.04%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Clear cell endometrial carcinoma		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	4 / 7372 (0.05%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	9 / 7372 (0.12%)	16 / 7344 (0.22%)
occurrences causally related to treatment / all	0 / 9	1 / 16
deaths causally related to treatment / all	0 / 1	0 / 3
Colon cancer metastatic		
subjects affected / exposed	2 / 7372 (0.03%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Colon cancer stage I		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Colorectal adenocarcinoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Colorectal cancer		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Desmoplastic melanoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Ear neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 7372 (0.01%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	2 / 7372 (0.03%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Epithelioid mesothelioma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Essential thrombocythaemia		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrosarcoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gallbladder cancer		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric adenoma		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	3 / 7372 (0.04%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 3
Gastric neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal carcinoma		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal submucosal tumour		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Glioblastoma multiforme		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemangioblastoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangioma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hairy cell leukaemia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic adenoma		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		
subjects affected / exposed	6 / 7372 (0.08%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 6	1 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Hepatocellular carcinoma		
subjects affected / exposed	5 / 7372 (0.07%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 3	0 / 2
Hodgkin's disease		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	1 / 7372 (0.01%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		

subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukaemia		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip neoplasm		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lip squamous cell carcinoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	4 / 7372 (0.05%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Lung adenocarcinoma metastatic		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	6 / 7372 (0.08%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 5	0 / 4
Lung carcinoma cell type unspecified stage IV		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	12 / 7372 (0.16%)	12 / 7344 (0.16%)
occurrences causally related to treatment / all	0 / 12	0 / 12
deaths causally related to treatment / all	0 / 9	0 / 7
Lung squamous cell carcinoma metastatic		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lymphoma		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant anorectal neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant ascites		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	7 / 7372 (0.09%)	8 / 7344 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant melanoma in situ		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant neoplasm progression		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant pleural effusion		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mantle cell lymphoma		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Melanocytic naevus		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesothelioma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mesothelioma malignant		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to adrenals		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to bone		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastasis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic renal cell carcinoma		

subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Metastatic uterine cancer		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Myeloid leukaemia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myeloproliferative neoplasm		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Nasal sinus cancer		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Neoplasm prostate		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		

subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Neuroendocrine carcinoma of the skin		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
Non-Hodgkin's lymphoma		
subjects affected / exposed	3 / 7372 (0.04%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Non-small cell lung cancer metastatic		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Non-small cell lung cancer stage IV		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Oesophageal adenocarcinoma		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal cancer metastatic		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	3 / 7372 (0.04%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Oropharyngeal cancer		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Ovarian neoplasm		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	15 / 7372 (0.20%)	15 / 7344 (0.20%)
occurrences causally related to treatment / all	2 / 15	1 / 15
deaths causally related to treatment / all	3 / 9	2 / 10
Pancreatic neuroendocrine tumour		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraproteinaemia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Parathyroid tumour benign		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Penile cancer		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral T-cell lymphoma unspecified		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	5 / 7372 (0.07%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	1 / 5	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer		
subjects affected / exposed	26 / 7372 (0.35%)	20 / 7344 (0.27%)
occurrences causally related to treatment / all	0 / 26	0 / 20
deaths causally related to treatment / all	0 / 1	0 / 1
Prostate cancer metastatic		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer recurrent		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Prostate cancer stage I		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	4 / 7372 (0.05%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	1 / 7372 (0.01%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer metastatic		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal neoplasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	7 / 7372 (0.09%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Renal cell carcinoma		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal oncocytoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory papilloma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal melanoma		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Salivary gland cancer		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seborrhoeic keratosis		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinonasal papilloma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Small intestine carcinoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Spinal meningioma benign		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		

subjects affected / exposed	13 / 7372 (0.18%)	12 / 7344 (0.16%)
occurrences causally related to treatment / all	0 / 16	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1
Squamous cell carcinoma of head and neck		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
Squamous cell carcinoma of skin		
subjects affected / exposed	8 / 7372 (0.11%)	7 / 7344 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the hypopharynx		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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 tongue		
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	7 / 7372 (0.09%)	14 / 7344 (0.19%)
occurrences causally related to treatment / all	1 / 7	2 / 14
deaths causally related to treatment / all	0 / 0	0 / 0

Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer metastatic			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	7 / 7372 (0.09%)	5 / 7344 (0.07%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma urethra			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	3 / 7372 (0.04%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Xanthogranuloma			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Arterial rupture			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bleeding varicose vein			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	1 / 7372 (0.01%)	8 / 7344 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocele			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			

subjects affected / exposed	3 / 7372 (0.04%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cephalo-pelvic disproportion			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pre-eclampsia			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	5 / 7372 (0.07%)	4 / 7344 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	5 / 7372 (0.07%)	5 / 7344 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

Complication associated with device			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug interaction			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granuloma			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic cyst			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired self-care		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site inflammation		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	79 / 7372 (1.07%)	87 / 7344 (1.18%)
occurrences causally related to treatment / all	0 / 90	1 / 104
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		

subjects affected / exposed	4 / 7372 (0.05%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	5 / 7372 (0.07%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food allergy			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			

subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Alcohol use			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrophic vulvovaginitis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	11 / 7372 (0.15%)	9 / 7344 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cystocele			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital lesion			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menorrhagia			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organic erectile dysfunction			

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	3 / 7372 (0.04%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian vein thrombosis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatomegaly		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine haemorrhage		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine polyp		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine prolapse		

subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acquired diaphragmatic eventration			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	10 / 7372 (0.14%)	8 / 7344 (0.11%)	
occurrences causally related to treatment / all	1 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Alveolitis allergic			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	4 / 7372 (0.05%)	5 / 7344 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthmatic crisis			

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	49 / 7372 (0.66%)	48 / 7344 (0.65%)
occurrences causally related to treatment / all	0 / 81	0 / 84
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	18 / 7372 (0.24%)	11 / 7344 (0.15%)
occurrences causally related to treatment / all	0 / 18	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		

subjects affected / exposed	4 / 7372 (0.05%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hiccups		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	7 / 7372 (0.09%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Interstitial lung disease		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum perforation		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal turbinate hypertrophy		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	10 / 7372 (0.14%)	9 / 7344 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural fibrosis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax spontaneous		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary fibrosis		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory acidosis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	13 / 7372 (0.18%)	12 / 7344 (0.16%)
occurrences causally related to treatment / all	0 / 14	0 / 13
deaths causally related to treatment / all	0 / 3	0 / 0
Restrictive pulmonary disease		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		
subjects affected / exposed	6 / 7372 (0.08%)	7 / 7344 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Stridor		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheal stenosis		
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheomalacia		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			

subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed mood		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	14 / 7372 (0.19%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 15	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	0 / 7372 (0.00%)	7 / 7344 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Personality change due to a general medical condition		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic stress disorder		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psychogenic seizure		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device battery issue			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
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	3 / 7372 (0.04%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patient-device incompatibility			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bile duct stenosis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cirrhosis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cyst			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatic failure			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cirrhosis alcoholic		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder fistula		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Hepatic haematoma		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic lesion		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic mass		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatomegaly			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatosplenomegaly			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Anticoagulation drug level increased			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood calcitonin increased			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophil count increased			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV test positive			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio abnormal			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Accidental overdose			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	7 / 7372 (0.09%)	11 / 7344 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod sting			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Comminuted fracture		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complicated fracture		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	3 / 7372 (0.04%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Contrast media reaction		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	4 / 7372 (0.05%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ear injury		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exposure to toxic agent		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye injury		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	14 / 7372 (0.19%)	12 / 7344 (0.16%)
occurrences causally related to treatment / all	0 / 15	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	6 / 7372 (0.08%)	10 / 7344 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	13 / 7372 (0.18%)	9 / 7344 (0.12%)
occurrences causally related to treatment / all	0 / 14	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		

subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	4 / 7372 (0.05%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body		
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal anastomotic leak		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria traumatic		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic haematoma		

subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	6 / 7372 (0.08%)	14 / 7344 (0.19%)
occurrences causally related to treatment / all	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	9 / 7372 (0.12%)	10 / 7344 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Ilium fracture		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	4 / 7372 (0.05%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		

subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament injury		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	5 / 7372 (0.07%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	7 / 7372 (0.09%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	3 / 7372 (0.04%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Muscle injury		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle strain		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nail injury		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	7 / 7372 (0.09%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	1 / 7	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	3 / 7372 (0.04%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perirenal haematoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post laminectomy syndrome		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative fever		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thoracic procedure complication		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation pneumonitis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		

subjects affected / exposed	14 / 7372 (0.19%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Scapula fracture		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin abrasion		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin injury		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue injury		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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 / 7372 (0.03%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury cervical		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic injury		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic rupture		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	9 / 7372 (0.12%)	11 / 7344 (0.15%)
occurrences causally related to treatment / all	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		

subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	8 / 7372 (0.11%)	8 / 7344 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	2 / 7372 (0.03%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Traumatic haemothorax		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic liver injury		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		

subjects affected / exposed	3 / 7372 (0.04%)	7 / 7344 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound evisceration			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous malformation			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic arteriovenous malformation			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hydrocele			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
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 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rathke's cleft cyst			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sacralisation			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalassaemia beta			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Amputation stump pain			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asterixis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic neuropathy			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	4 / 7372 (0.05%)	5 / 7344 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar haemorrhage			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar syndrome			

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	5 / 7372 (0.07%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrospinal fluid leakage		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical myelopathy		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
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	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicogenic headache		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		

subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Coordination abnormal		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelinating polyneuropathy		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	9 / 7372 (0.12%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 9	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	4 / 7372 (0.05%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	2 / 7372 (0.03%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		

subjects affected / exposed	6 / 7372 (0.08%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Frontotemporal dementia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	3 / 7372 (0.04%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		

subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotonia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic generalised epilepsy		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial pressure increased		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		

subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral radiculopathy		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	2 / 7372 (0.03%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Mixed dementia		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Myelitis transverse		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve root compression		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgic amyotrophy		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuritis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurodegenerative disorder		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		

subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post herpetic neuralgia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke seizure		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular syndrome		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Restless legs syndrome		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	1 / 7372 (0.01%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	10 / 7372 (0.14%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Senile dementia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal claudication		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subacute combined cord degeneration		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural hygroma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal neuralgia		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
VIth nerve paralysis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular headache		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		

subjects affected / exposed	4 / 7372 (0.05%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	26 / 7372 (0.35%)	15 / 7344 (0.20%)	
occurrences causally related to treatment / all	0 / 31	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Antiphospholipid syndrome			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow disorder			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow oedema			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemolytic anaemia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	3 / 7372 (0.04%)	11 / 7344 (0.15%)
occurrences causally related to treatment / all	0 / 3	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastocytosis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed deafness			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane disorder			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	6 / 7372 (0.08%)	6 / 7344 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	0 / 7372 (0.00%)	6 / 7344 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extraocular muscle disorder			

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye disorder		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye pain		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lens dislocation		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular hole		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	6 / 7372 (0.08%)	7 / 7344 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal strangulated hernia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal haemorrhage		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anorectal stenosis		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anorectal varices		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		

subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic hernia		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	0 / 7372 (0.00%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		

subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis haemorrhagic		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	1 / 7372 (0.01%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocele		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocutaneous fistula		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epigastric discomfort		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		

subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric antral vascular ectasia		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric fistula		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric perforation		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	0 / 7372 (0.00%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric varices haemorrhage		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	12 / 7372 (0.16%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	1 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal haemorrhage		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	34 / 7372 (0.46%)	27 / 7344 (0.37%)
occurrences causally related to treatment / all	1 / 37	1 / 30
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal hypomotility		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal melanosis		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal obstruction		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	9 / 7372 (0.12%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	1 / 10	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival bleeding		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		

subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated umbilical hernia		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammatory bowel disease		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	4 / 7372 (0.05%)	9 / 7344 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haematoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	3 / 7372 (0.04%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jejunal perforation		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer haemorrhage		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	10 / 7372 (0.14%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 11	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	9 / 7372 (0.12%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar hernia		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal obstruction		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal perforation		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal polyp		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral dysaesthesia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oroantral fistula		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic mass		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	22 / 7372 (0.30%)	37 / 7344 (0.50%)
occurrences causally related to treatment / all	2 / 24	3 / 37
deaths causally related to treatment / all	2 / 2	0 / 0
Peptic ulcer		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal haematoma		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	3 / 7372 (0.04%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectourethral fistula		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal mass		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		
subjects affected / exposed	8 / 7372 (0.11%)	7 / 7344 (0.10%)
occurrences causally related to treatment / all	1 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal perforation		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated umbilical hernia		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue haemorrhage		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	14 / 7372 (0.19%)	5 / 7344 (0.07%)	
occurrences causally related to treatment / all	0 / 14	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	10 / 7372 (0.14%)	9 / 7344 (0.12%)	
occurrences causally related to treatment / all	0 / 10	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	5 / 7372 (0.07%)	5 / 7344 (0.07%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis atopic		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis bullous		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug eruption		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug reaction with eosinophilia and systemic symptoms		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Granuloma skin		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ingrowing nail		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keloid scar		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen planus		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lichenoid keratosis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parapsoriasis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prurigo		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash generalised		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical haemorrhage			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder discomfort			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder diverticulum			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder mass			

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	5 / 7372 (0.07%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis chronic		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	7 / 7372 (0.09%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	4 / 7372 (0.05%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonic bladder		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotonic urinary bladder		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	13 / 7372 (0.18%)	15 / 7344 (0.20%)
occurrences causally related to treatment / all	0 / 13	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrosclerosis		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive uropathy		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-ureteric obstruction		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	3 / 7372 (0.04%)	8 / 7344 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst haemorrhage		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		
subjects affected / exposed	3 / 7372 (0.04%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	5 / 7372 (0.07%)	10 / 7344 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral haemorrhage		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	2 / 7372 (0.03%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder polyp		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	7 / 7372 (0.09%)	4 / 7344 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal mass			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune thyroiditis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cushing's syndrome			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	3 / 7372 (0.04%)	7 / 7344 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperaldosteronism			

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid disorder			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	9 / 7372 (0.12%)	5 / 7344 (0.07%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			

subjects affected / exposed	3 / 7372 (0.04%)	6 / 7344 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Arthrofibrosis		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropathy		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Articular calcification		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	12 / 7372 (0.16%)	14 / 7344 (0.19%)
occurrences causally related to treatment / all	0 / 14	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)
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	1 / 7372 (0.01%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall haematoma		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	3 / 7372 (0.04%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Crystal arthropathy		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Deformity thorax		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture nonunion		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		

subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc compression		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	4 / 7372 (0.05%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	4 / 7372 (0.05%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	17 / 7372 (0.23%)	15 / 7344 (0.20%)
occurrences causally related to treatment / all	0 / 19	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc space narrowing		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint adhesion		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint effusion		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint instability		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
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	20 / 7372 (0.27%)	12 / 7344 (0.16%)
occurrences causally related to treatment / all	0 / 21	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscal degeneration		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Monarthrititis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	5 / 7372 (0.07%)	10 / 7344 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal deformity		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		

subjects affected / exposed	6 / 7372 (0.08%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myopathy		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myositis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic arthropathy		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	79 / 7372 (1.07%)	69 / 7344 (0.94%)
occurrences causally related to treatment / all	0 / 89	0 / 76
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondritis		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	4 / 7372 (0.05%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periostitis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritits		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		

subjects affected / exposed	0 / 7372 (0.00%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatic disorder		
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	1 / 7372 (0.01%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	9 / 7372 (0.12%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Sacroiliitis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	10 / 7372 (0.14%)	4 / 7344 (0.05%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal disorder		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	9 / 7372 (0.12%)	11 / 7344 (0.15%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		

subjects affected / exposed	3 / 7372 (0.04%)	3 / 7344 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spondyloarthropathy		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	6 / 7372 (0.08%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Synovitis		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon pain		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendonitis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral foraminal stenosis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral osteophyte		

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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			
Bronchitis			
subjects affected / exposed	2 / 7372 (0.03%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic tonsillitis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			

subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis E		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster oticus		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keratouveitis		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (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	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	0 / 7372 (0.00%)	2 / 7344 (0.03%)	
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 / 7372 (0.00%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	8 / 7372 (0.11%)	10 / 7344 (0.14%)	
occurrences causally related to treatment / all	1 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	5 / 7372 (0.07%)	2 / 7344 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid overload			
subjects affected / exposed	2 / 7372 (0.03%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			

subjects affected / exposed	2 / 7372 (0.03%)	5 / 7344 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypernatraemia		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 7372 (0.01%)	0 / 7344 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	2 / 7372 (0.03%)	2 / 7344 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	2 / 7372 (0.03%)	8 / 7344 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	1 / 7372 (0.01%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lactose intolerance		

subjects affected / exposed	0 / 7372 (0.00%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	9 / 7372 (0.12%)	1 / 7344 (0.01%)
occurrences causally related to treatment / all	0 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Placebo	EQW 2 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 7372 (0.00%)	0 / 7344 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 November 2010	<p>Amylin Pharmaceuticals, Inc., sponsor of the IND in the US and Puerto Rico, transferred clinical sponsor obligations to Eli Lilly and Company for the conduct of the study outside the US, Puerto Rico, and Canada.</p> <p>Monitoring of serum calcitonin throughout the trial was added, specifying collection at baseline, annually, and trial termination.</p> <p>Storage temperatures for the diluent were revised from between 2°C and 27°C to between 2°C and 25°C.</p> <p>Injection site specification was expanded to the thigh and back of the upper arm in addition to the abdomen.</p> <p>Collection of AEs leading to discontinuation was restricted to SAEs.</p> <p>Events of pancreatitis and neoplasia were specified as to be treated as SAEs, collected and reported as ancillary events.</p> <p>The SAC was added to provide operational oversight across all participating institutions.</p>
10 May 2011	<p>Inclusion criteria were expanded to include patients taking insulin who had been using a stable dose of insulin ($\pm 20\%$ of the scheduled total daily insulin dose), either alone or in combination with a stable dose of metformin for at least 3 months).</p> <p>Exclusion criteria were expanded to restrict patients with a history (≥ 2 episodes) of severe hypoglycemia within 12 months of enrollment.</p> <p>Exclusion criteria were expanded to restrict patients with a personal or family history of medullary thyroid cancer or Multiple Endocrine Neoplasia Type 2 or serum calcitonin level >40 ng/L at baseline.</p> <p>Criterion for discontinuing trial drug was set to ≥ 50 ng/L of serum calcitonin.</p>
23 April 2012	<p>Inclusion criteria were changed to allow patients with an HbA1c $\geq 6.5\%$ and using insulin, alone or in combination with oral antihyperglycemic medications, to enroll in the study.</p> <p>The requirement for patients to have been on a stable dose of oral antihyperglycemic medication was removed</p>
12 September 2012	<p>References to sponsorship by Eli Lilly and Company were deleted, and Amylin assumed sole sponsorship of the study.</p>

25 October 2013	Based on blinded review of accrued data, the event rate for the primary composite CV endpoint was approximately 2.2 per 100 patient-years, which was less than the anticipated rate of 3.8 per 100 patient-years. To achieve completion of the study within the commitment date of the FDA Post- Marketing Request, a number of measures were taken: The power of the study to achieve the primary objective of superiority of EQW versus PBO with regard to the primary composite CV endpoint was reduced from 90% to 85% resulting in a reduction of the targeted number of events from 1591 to 1360. The total number of patients to be enrolled to achieve the targeted number of events was increased from 9500 to 14000. The proportion of patients enrolled with a prior history of a CV event was increased from 60% to 80% (for newly enrolled patients). Since more than 7000 patients had been enrolled under the 60:40 scheme, it was anticipated that the ratio of patients with prior history of CV event to those with no prior CV event would be approximately 70:30 at study end. It was anticipated that more than 4000 patients (around 30%) without any prior CV history would be enrolled in the study. The minimum follow-up duration of 4 years for a patient was eliminated. The following changes were also made: The secondary hypothesis of non-inferiority of EQW vs PBO regarding the primary composite CV endpoint was updated to a primary safety hypothesis. The end of study procedures was clarified. Clarifications were made to the specifications around withdrawal of consent, lost-to-follow-up procedures, and the follow-up phone call for safety purposes after end-of-study discontinuation of study treatment. Updates to planned interim analyses to match the change in planned total number of events were made as specified in the DSMB charter. Administrative changes, such as requirements for reporting of a potential serious breach of GCP, record retention, source documentation, CRF completion and the CSR were made.
09 March 2016	The time period for inclusion of primary endpoints was extended past the primary endpoint cut-off date to the trial termination visit. Procedures for handling Clinical Events were changed so that such events would be collected and reported in the same way both pre- and post-cut-off date. An on-treatment (through the last dose of study medication or the trial termination visit, whichever occurred first) analysis of the ITT population was included for the primary and some secondary endpoints as sensitivity analyses. Administrative changes noted the replacement of Professor Robert Califf by Dr. Adrian Felipe Hernandez. Administrative note was made of the fact that Amylin remained the sponsor of the study, but that Amylin was now a wholly-owned subsidiary of AstraZeneca.

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.

Only SAE are collected in this study.

Notes: