



## Clinical trial results:

### Study to evaluate GSK Biologicals' Herpes Zoster vaccine GSK1437173A in adults aged $\geq 50$ years

#### Summary

EudraCT number	2008-000367-42
Trial protocol	ES FI FR DE GB SE EE IT CZ
Global end of trial date	27 July 2015

#### Results information

Result version number	v2 (current)
This version publication date	03 March 2021
First version publication date	10 August 2016
Version creation reason	<ul style="list-style-type: none"><li>• Correction of full data set</li></ul> Results have been amended to account for consistency with other registries.

#### Trial information

##### Trial identification

Sponsor protocol code	110390
-----------------------	--------

##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01165177
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.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	09 May 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 May 2014
Global end of trial reached?	Yes
Global end of trial date	27 July 2015
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To evaluate VE in the prevention of HZ compared to placebo in adults 50 YOA, as measured by the reduction in herpes zoster (HZ) risk.

Protection of trial subjects:

The vaccine/product recipients were to be observed closely for at least 30 minutes, with appropriate medical treatment readily available in case of a rare anaphylactic reaction following the administration of vaccine/product. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Subjects were followed-up for 30 days after the last vaccination/product administration.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 August 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 418
Country: Number of subjects enrolled	Brazil: 634
Country: Number of subjects enrolled	Canada: 631
Country: Number of subjects enrolled	Czech Republic: 905
Country: Number of subjects enrolled	Estonia: 1110
Country: Number of subjects enrolled	Finland: 1422
Country: Number of subjects enrolled	France: 624
Country: Number of subjects enrolled	Germany: 789
Country: Number of subjects enrolled	Hong Kong: 470
Country: Number of subjects enrolled	Italy: 358
Country: Number of subjects enrolled	Japan: 577
Country: Number of subjects enrolled	Korea, Republic of: 539
Country: Number of subjects enrolled	Mexico: 914
Country: Number of subjects enrolled	Spain: 1057
Country: Number of subjects enrolled	Sweden: 1013
Country: Number of subjects enrolled	Taiwan: 1281
Country: Number of subjects enrolled	United Kingdom: 619
Country: Number of subjects enrolled	United States: 2068

Worldwide total number of subjects	15429
EEA total number of subjects	7897

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)	9618
From 65 to 84 years	5628
85 years and over	183

## Subject disposition

### Recruitment

Recruitment details:

Apportionment of approximately 20-25% of the  $\geq 70$  YOA cohort to persons  $\geq 80$  YOA ensures that this particularly vulnerable population is adequately represented.

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

Number of subjects started	15429
----------------------------	-------

Number of subjects completed	15405
------------------------------	-------

### Pre-assignment subject non-completion reasons

Reason: Number of subjects	Study vaccine not received: 24
----------------------------	--------------------------------

### Period 1

Period 1 title	Overall Study (overall period)
----------------	--------------------------------

Is this the baseline period?	Yes
------------------------------	-----

Allocation method	Randomised - controlled
-------------------	-------------------------

Blinding used	Double blind
---------------	--------------

Roles blinded	Investigator, Assessor, Subject
---------------	---------------------------------

### Arms

Are arms mutually exclusive?	Yes
------------------------------	-----

<b>Arm title</b>	GSK1437173A Group
------------------	-------------------

Arm description:

Subjects received herpes zoster subunit vaccine (gE/AS01B vaccine: GSK1437173A) according to a 0, 2-month schedule.

Arm type	Experimental
----------	--------------

Investigational medicinal product name	GSK1437173A
--	-------------

Investigational medicinal product code	
--	--

Other name	gE-AS01B
------------	----------

Pharmaceutical forms	Powder and solvent for suspension for injection
----------------------	---

Routes of administration	Intramuscular use
--------------------------	-------------------

Dosage and administration details:

The study product was administered according to a 0, 2-month schedule.

<b>Arm title</b>	Placebo Group
------------------	---------------

Arm description:

Subjects received saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Arm type	Placebo
----------	---------

Investigational medicinal product name	Placebo
--	---------

Investigational medicinal product code	
--	--

Other name	Saline solution
------------	-----------------

Pharmaceutical forms	Solution for injection
----------------------	------------------------

Routes of administration	Intramuscular use
--------------------------	-------------------

Dosage and administration details:

The study product was administered according to a 0, 2-month schedule.

<b>Number of subjects in period 1<sup>[1]</sup></b>	GSK1437173A Group	Placebo Group
Started	7695	7710
Completed	6773	6808
Not completed	922	902
Suspected HZ episode	-	2
Consent withdrawn by subject	368	354
Non-serious adverse events	30	18
Migrated/ moved from study area	48	43
Serious adverse events	227	235
Lost to follow-up	183	194
Other unspecified reasons	47	35
Protocol deviation	19	21

---

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Out of the 15429 subjects enrolled in the trial, 24 were assigned codes but did not receive vaccination, hence they were excluded from the study start.

## Baseline characteristics

### Reporting groups

Reporting group title	GSK1437173A Group
-----------------------	-------------------

Reporting group description:

Subjects received herpes zoster subunit vaccine (gE/AS01B vaccine: GSK1437173A) according to a 0, 2-month schedule.

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

Reporting group description:

Subjects received saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Reporting group values	GSK1437173A Group	Placebo Group	Total
Number of subjects	7695	7710	15405
Age categorical			
Units: Subjects			

Age continuous			
Age continuous description			
Units: years			
arithmetic mean	62.4	62.3	
standard deviation	± 9	± 9	-
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	4709	4711	9420
Male	2986	2999	5985

## End points

### End points reporting groups

Reporting group title	GSK1437173A Group
Reporting group description: Subjects received herpes zoster subunit vaccine (gE/AS01B vaccine: GSK1437173A) according to a 0, 2-month schedule.	
Reporting group title	Placebo Group
Reporting group description: Subjects received saline solution (NaCl solution) as control according to a 0, 2-month schedule.	
Subject analysis set title	GSK1437173A 50-59 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged between 50 and 59 years of age (YOA), receiving the GSK1437173A vaccine according to a 0, 2-month schedule.	
Subject analysis set title	GSK1437173A 60-69 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged between 60 and 69 years of age (YOA), receiving the GSK1437173A vaccine according to a 0, 2-month schedule.	
Subject analysis set title	GSK1437173A Over 70 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged above 70 years of age (YOA), receiving the GSK1437173A vaccine according to a 0, 2-month schedule.	
Subject analysis set title	GSK1437173A Overall Ages Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged over 50 years of age (YOA), receiving the GSK1437173A vaccine according to a 0, 2-month schedule.	
Subject analysis set title	Placebo 50-59 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged between 50 and 59 years of age (YOA), receiving placebo according to a 0, 2-month schedule.	
Subject analysis set title	Placebo 60-69 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged between 60 and 69 years of age (YOA), receiving placebo according to a 0, 2-month schedule.	
Subject analysis set title	Placebo Over 70 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged above 70 years of age (YOA), receiving placebo according to a 0, 2-month schedule.	
Subject analysis set title	Placebo Overall Ages Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects aged over 50 years of age (YOA), receiving placebo according to a 0, 2-month schedule.	

**Primary: Number of subjects with confirmed Herpes zoster (HZ) cases**

End point title	Number of subjects with confirmed Herpes zoster (HZ) cases
-----------------	--

End point description:

Confirmed HZ cases during the study were assessed in the Modified Total Vaccinated Cohort (mTVc)

End point type	Primary
----------------	---------

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3492	2141	1711	7344
Units: Subjects	3	2	1	6

End point values	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3525	2166	1724	7415
Units: Subjects	87	75	48	210

**Statistical analyses**

Statistical analysis title	Statistical analysis 1
----------------------------	------------------------

Statistical analysis description:

Comparison of vaccine efficacy in prevention of HZ between GSK1437173A 50-59 YOA group and placebo 50-59 YOA group

Comparison groups	Placebo 50-59 YOA Group v GSK1437173A 50-59 YOA Group
Number of subjects included in analysis	7017
Analysis specification	Pre-specified
Analysis type	other <sup>[1]</sup>
P-value	< 0.0001 <sup>[2]</sup>
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	96.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	89.6
upper limit	99.3

Notes:

[1] - Criteria for the vaccine efficacy (VE) objective of herpes zoster subunit (HZ/su) vaccine against herpes zoster (HZ) disease, in the 50-59 YOA age strata : The lower limit (LL) of the two-sided 95% confidence interval (CI) of VE had to be above 10%.

[2] - Two sided exact P-value conditional to number of cases.

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description: Comparison of vaccine efficacy in prevention of HZ between GSK1437173A over 60-69 YOA group and placebo over 60-69 YOA group	
Comparison groups	Placebo 60-69 YOA Group v GSK1437173A 60-69 YOA Group
Number of subjects included in analysis	4307
Analysis specification	Pre-specified
Analysis type	other <sup>[3]</sup>
P-value	< 0.0001 <sup>[4]</sup>
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	97.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	90.1
upper limit	99.7

Notes:

[3] - Criteria for the VE objective of HZ/su vaccine against herpes zoster disease, in the 60-69 YOA age strata : The lower limit (LL) of the two-sided 95% confidence interval (CI) of VE had to be above 10%.

[4] - Two sided exact P-value conditional to number of cases.

<b>Statistical analysis title</b>	Statistical analysis 3
Statistical analysis description: Comparison of vaccine efficacy in prevention of HZ between GSK1437173A over 70 YOA group and placebo over 70 YOA group	
Comparison groups	GSK1437173A Over 70 YOA Group v Placebo Over 70 YOA Group
Number of subjects included in analysis	3435
Analysis specification	Pre-specified
Analysis type	other <sup>[5]</sup>
P-value	= 0.0001 <sup>[6]</sup>
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	97.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	87.9
upper limit	100

Notes:

[5] - Criteria for the VE objective of HZ/su vaccine against herpes zoster disease, in the 70-79 YOA age strata : The lower limit (LL) of the two-sided 95% confidence interval (CI) of VE had to be above 10%.

[6] - Two sided exact P-value conditional to number of cases.

<b>Statistical analysis title</b>	Statistical analysis 4
-----------------------------------	------------------------

Statistical analysis description:

Comparison of vaccine efficacy in prevention of HZ between GSK1437173A overall ages group and placebo overall ages group

Comparison groups	Placebo Overall Ages Group v GSK1437173A Overall Ages Group
Number of subjects included in analysis	14759
Analysis specification	Pre-specified
Analysis type	other <sup>[7]</sup>
P-value	< 0.0001 <sup>[8]</sup>
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	97.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	93.7
upper limit	99

Notes:

[7] - Criteria for the VE objective of HZ/su vaccine against herpes zoster disease, in the overall age strata : The lower limit (LL) of the two-sided 95% confidence interval (CI) of VE had to be above 10%.

[8] - Two sided exact P-value conditional to number of cases.

**Secondary: Number of subjects with any episodes of Post-Herpetic Neuralgia (PHN)**

End point title	Number of subjects with any episodes of Post-Herpetic Neuralgia (PHN)
End point description:	The incidence of PHN was calculated using the modified total vaccinated cohort.
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

End point values	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3491	2140	1709	7430
Units: Subjects	0	0	0	0

End point values	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3523	2166	1724	7413
Units: Subjects	8	2	8	18

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
-----------------------------------	------------------------

Statistical analysis description:

Comparison of vaccine efficacy in prevention of PHN between GSK1437173A 50-59 YOA group and placebo 50-59 YOA group

Comparison groups	GSK1437173A 50-59 YOA Group v Placebo 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other <sup>[9]</sup>
P-value	= 0.0081
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.9
upper limit	100

Notes:

[9] - Criteria for the VE objective of HZ/su vaccine against PostHerpetic Neuralgia (PHN): The lower limit of the 95% CI of VE had to be above 0%

<b>Statistical analysis title</b>	Statistical analysis 2
-----------------------------------	------------------------

Statistical analysis description:

Comparison of vaccine efficacy in prevention of PHN between GSK1437173A 60-69 YOA group and placebo 60-69 YOA group

Comparison groups	Placebo 60-69 YOA Group v GSK1437173A 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other <sup>[10]</sup>
P-value	= 0.5097
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	-442.8
upper limit	100

Notes:

[10] - Criteria for VE of HZ/su vaccine against PHN: The lower limit of the 95% CI of VE had to be above 0%

<b>Statistical analysis title</b>	Statistical analysis 3
-----------------------------------	------------------------

Statistical analysis description:

Comparison of vaccine efficacy in prevention of PHN between GSK1437173A over 70 YOA group and placebo over 70 YOA group

Comparison groups	GSK1437173A Over 70 YOA Group v Placebo Over 70 YOA Group
-------------------	---

Number of subjects included in analysis	3433
Analysis specification	Pre-specified
Analysis type	other <sup>[11]</sup>
P-value	= 0.0078
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.4
upper limit	100

Notes:

[11] - Criteria for the VE objective of HZ/su vaccine against PHN: The lower limit of the 95% CI of VE had to be above 0%

<b>Statistical analysis title</b>	Statistical analysis 4
-----------------------------------	------------------------

Statistical analysis description:

Comparison of vaccine efficacy in prevention of PHN between GSK1437173A overall ages group and placebo overall ages group

Comparison groups	Placebo Overall Ages Group v GSK1437173A Overall Ages Group
Number of subjects included in analysis	14843
Analysis specification	Pre-specified
Analysis type	other <sup>[12]</sup>
P-value	< 0.0001
Method	Poisson exact test
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	77.1
upper limit	100

Notes:

[12] - Criteria for the VE objective of HZ/su vaccine against PHN: The lower limit of the 95% CI of VE had to be above 0%

### **Secondary: Number of subjects with a reduction of duration of severe 'worst' HZ-associated pain**

End point title	Number of subjects with a reduction of duration of severe 'worst' HZ-associated pain
-----------------	--

End point description:

Severe 'worst' pain was defined as HZ-associated pain rated as 3 or above on the 'worst pain' Zoster Brief Pain Inventory (ZBPI) questionnaire. The outcome assessed the duration of severe 'worst' HZ-associated pain following the onset of a confirmed HZ rash over the entire pain reporting period as measured by the ZBPI in subjects with confirmed HZ. This analysis involved any subject reporting clinically significant pain (i.e. pain with a score of 3 or more on a 0-10 point scale) at any time during the study.

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

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	2	9
Units: Subjects	4	1	2	7

<b>End point values</b>	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	90	61	254
Units: Subjects	91	74	56	221

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with confirmed HZ episode related mortality

End point title	Number of subjects with confirmed HZ episode related mortality
End point description:	The analysis focused on the number of subjects who died due to HZ
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3491	2140	1709	7340
Units: Subjects	0	0	0	0

<b>End point values</b>	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3523	2166	1724	7413
Units: Subjects	0	0	0	0

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with HZ related complications

End point title	Number of subjects with HZ related complications
End point description:	The analysis focused on the incidence of HZ complications in subjects with confirmed HZ
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

End point values	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	2	9
Units: Subjects	0	0	0	0

End point values	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	90	61	254
Units: Subjects	1	3	2	6

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with confirmed HZ episode related hospitalizations

End point title	Number of subjects with confirmed HZ episode related hospitalizations
End point description:	The analysis focused on confirmed HZ episode related hospitalizations.
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3491	2140	1709	7340
Units: Subjects	0	0	0	0

<b>End point values</b>	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3523	2166	1724	7413
Units: Subjects	0	0	0	0

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with a confirmed HZ episode having a reduction of duration of pain medication associated with HZ

End point title	Number of subjects with a confirmed HZ episode having a reduction of duration of pain medication associated with HZ
-----------------	---

End point description:

The analysis focused on patients who experienced a reduction in duration of pain medication administered for HZ in subjects with confirmed HZ

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

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	2	9
Units: Subjects	3	2	1	6

<b>End point values</b>	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	90	61	254
Units: Subjects	82	63	45	190

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with a confirmed HZ episode taking pain medication associated with HZ

End point title	Number of subjects with a confirmed HZ episode taking pain medication associated with HZ
End point description:	The analysis focused on subjects taking pain medication due to HZ
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

End point values	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	2	9
Units: Subjects	3	2	1	6

End point values	Placebo 50-59 YOY Group	Placebo 60-69 YOY Group	Placebo Over 70 YOY Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	90	61	254
Units: Subjects	82	63	45	190

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of days with severe 'worst' HZ-associated pain

End point title	Number of days with severe 'worst' HZ-associated pain
End point description:	Severe 'worst' pain was defined as HZ-associated pain rated as 3 or above on the 'worst pain' ZBPI questionnaire. This Outcome Measure was only assessed participants with confirmed HZ. This analysis involved any subject reporting ZBPI clinically significant pain (i.e. pain with a score of 3 or more on a 0-10 point scale) at any time during the study.
End point type	Secondary

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	2	7
Units: Days				
arithmetic mean (standard deviation)	12 ( $\pm$ 11.8)	78 ( $\pm$ 0)	9 ( $\pm$ 4.2)	20.6 ( $\pm$ 26.8)

<b>End point values</b>	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	91	74	56	221
Units: Days				
arithmetic mean (standard deviation)	28.7 ( $\pm$ 48.4)	21.6 ( $\pm$ 29.3)	44 ( $\pm$ 74.4)	30.2 ( $\pm$ 51.9)

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with confirmed HZ episode related mortality and hospitalizations

End point title	Number of subjects with confirmed HZ episode related mortality and hospitalizations
-----------------	---

End point description:

The analysis focused on confirmed HZ episode related hospitalizations and deaths.

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

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3491	2140	1709	7340
Units: Subjects				
Mortality	0	0	0	0
Hospitalization	0	0	0	0
Mortality or hospitalization	0	0	0	0

<b>End point values</b>	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3523	2166	1724	7413
Units: Subjects				
Mortality	0	0	0	0
Hospitalization	0	0	0	0
Mortality or hospitalization	0	0	0	0

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with HZ related complications, by complication type

End point title	Number of subjects with HZ related complications, by complication type
-----------------	--

End point description:

Complication types included HZ vasculitis, Disseminated Disease, Ophtalmic Disease, Neurologic Disease, Visceral Disease and Stroke. This Outcome Measure was only assessed on participants with confirmed HZ.

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

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	2	9
Units: Subjects				
At least one complication	0	0	0	0
HZ vasculitis	0	0	0	0
Disseminated Disease	0	0	0	0
Ophtalmic Disease	0	0	0	0
Neurologic Disease	0	0	0	0
Visceral Disease	0	0	0	0
Stroke	0	0	0	0

<b>End point values</b>	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	90	61	254

Units: Subjects				
At least one complication	1	3	2	6
HZ vasculitis	0	1	0	1
Disseminated Disease	1	1	2	4
Ophthalmic Disease	0	1	0	1
Neurologic Disease	0	0	0	0
Visceral Disease	0	0	0	0
Stroke	0	0	0	0

## Statistical analyses

No statistical analyses for this end point

### Secondary: Distribution of pain medication associated with HZ

End point title	Distribution of pain medication associated with HZ
End point description:	The distribution of pain medication included 1 to 3 or more separate medications. This Outcome Measure was only assessed on participants with confirmed HZ.
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

End point values	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	2	9
Units: Subjects				
At least one pain medication	3	2	1	6
1 pain medication only	1	1	0	2
2 pain medications only	1	1	0	2
3 pain medications or more	1	0	1	2

End point values	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	90	61	254
Units: Subjects				
At least one pain medication	82	63	45	190
1 pain medication only	30	23	14	67
2 pain medications only	26	19	9	54
3 pain medications or more	26	21	22	69

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of days of pain medication associated with HZ

End point title | Number of days of pain medication associated with HZ

End point description:

The analysis was performed in subjects with a confirmed HZ episode

End point type | Secondary

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	GSK1437173A 50-59 YOA Group	GSK1437173A 60-69 YOA Group	GSK1437173A Over 70 YOA Group	GSK1437173A Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	1	6
Units: Days				
arithmetic mean (standard deviation)	17.3 ( $\pm$ 14.5)	20.5 ( $\pm$ 16.3)	63 ( $\pm$ 0)	26 ( $\pm$ 21.6)

End point values	Placebo 50-59 YOA Group	Placebo 60-69 YOA Group	Placebo Over 70 YOA Group	Placebo Overall Ages Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	82	63	45	190
Units: Days				
arithmetic mean (standard deviation)	49.2 ( $\pm$ 121.5)	74.3 ( $\pm$ 166.3)	127.7 ( $\pm$ 266.9)	76.1 ( $\pm$ 181.5)

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any and grade 3 solicited local symptoms

End point title | Number of subjects with any and grade 3 solicited local symptoms

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = Significant pain at rest that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site.

Relationship analysis was not performed.

End point type	Secondary
End point timeframe:	
During the 7-day (Days 0-6) post-vaccination period	

End point values	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4379	4375		
Units: Subjects				
Any Pain, Dose 1 (N=4359,4361)	3120	352		
Grade 3 Pain, Dose 1 (N=4359,4361)	159	6		
Any Redness, Dose 1 (N=4359,4361)	1225	40		
Grade 3 Redness, Dose 1 (N=4359,4361)	82	0		
Any Swelling, Dose 1 (N=4359,4361)	810	31		
Grade 3 Swelling, Dose 1 (N=4359,4361)	28	0		
Any Pain, Dose 2 (N=4207,4224)	2807	258		
Grade 3 Pain, Dose 2 (N=4207,4224)	185	10		
Any Redness, Dose 2 (N=4207,4224)	1151	24		
Grade 3 Redness, Dose 2 (N=4207,4224)	56	0		
Any Swelling, Dose 2 (N=4207,4224)	762	17		
Grade 3 Swelling, Dose 2 (N=4207,4224)	18	0		
Any Pain, Overall (N=4379,4375)	3463	490		
Grade 3 Pain, Overall (N=4379,4375)	293	16		
Any Redness, Overall (N=4379,4375)	1665	59		
Grade 3 Redness, Overall (N=4379,4375)	121	0		
Any Swelling, Overall (N=4379,4375)	1153	46		
Grade 3 Swelling, Overall (N=4379,4375)	43	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with any, grade 3 and related solicited general symptoms

End point title	Number of subjects with any, grade 3 and related solicited general symptoms
-----------------	---

End point description:

Assessed solicited general symptoms were fatigue, GI (gastrointestinal) symptoms (included nausea, vomiting, diarrhoea and/or abdominal pain), fever [defined as oral, axillary, rectal or tympanic temperature equal to or above 37.5 degrees Celsius (°C)], headache, myalgia, shivering and sweating. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary
End point timeframe:	
Within the 7-day (Days 0-6) post-vaccination period	

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4372	4376		
Units: Subjects				
Any Fatigue, Dose 1 (N=4346,4362)	1395	531		
Grade 3 Fatigue, Dose 1 (N=4346,4362)	109	29		
Related fatigue, Dose 1 (N=4346,4362)	1153	355		
Any GI symptoms, Dose 1 (N=4346,4362)	465	263		
Grade 3 GI symptoms, Dose 1 (N=4346,4362)	30	12		
Related GI symptoms, Dose 1 (N=4346,4362)	317	141		
Any Headache, Dose 1 (N=4346,4362)	1112	511		
Grade 3 Headache, Dose 1 (N=4346,4362)	67	20		
Related Headache, Dose 1 (N=4346,4362)	891	341		
Any Myalgia, Dose 1 (N=4346,4362)	1446	377		
Grade 3 Myalgia, Dose 1 (N=4346,4362)	104	21		
Related Myalgia, Dose 1 (N=4346,4362)	1231	265		
Any Shivering, Dose 1 (N=4346,4362)	632	166		
Grade 3 Shivering, Dose 1 (N=4346,4362)	69	3		
Related Shivering, Dose 1 (N=4346,4362)	539	104		
Any Temperature, Dose 1 (N=4346,4362)	500	65		
Grade 3 Temperature, Dose 1 (N=4346,4362)	7	1		
Related Temperature, Dose 1 (N=4346,4362)	420	38		
Any Fatigue, Dose 2 (N=4205,4222)	1456	379		
Grade 3 Fatigue, Dose 2 (N=4205,4222)	157	18		
Related fatigue, Dose 2 (N=4205,4222)	1270	279		
Any GI symptoms, Dose 2 (N=4205,4222)	495	183		
Grade 3 GI symptoms, Dose 2 (N=4205,4222)	33	14		
Related GI symptoms, Dose 2 (N=4205,4222)	392	91		
Any Headache, Dose 2 (N=4205,4222)	1249	340		
Grade 3 Headache, Dose 2 (N=4205,4222)	105	13		
Related Headache, Dose 2 (N=4205,4222)	1107	219		
Any Myalgia, Dose 2 (N=4205,4222)	1474	274		
Grade 3 Myalgia, Dose 2 (N=4205,4222)	160	13		

Related Myalgia, Dose 2 (N=4205,4222)	1314	197		
Any Shivering, Dose 2 (N=4205,4222)	947	128		
Grade 3 Shivering, Dose 2 (N=4205,4222)	139	9		
Related Shivering, Dose 2 (N=4205,4222)	838	88		
Any Temperature, Dose 2 (N=4205,4222)	645	72		
Grade 3 Temperature, Dose 2 (N=4205,4222)	8	5		
Related Temperature, Dose 2 (N=4205,4222)	571	40		
Any Fatigue, Overall (N=4372,4376)	2006	728		
Grade 3 Fatigue, Overall (N=4372,4376)	241	46		
Related fatigue, Overall (N=4372,4376)	1724	522		
Any GI symptoms, Overall (N=4372,4376)	787	386		
Grade 3 GI symptoms, Overall (N=4372,4376)	61	25		
Related GI symptoms, Overall (N=4372,4376)	591	206		
Any Headache, Overall (N=4372,4376)	1714	700		
Grade 3 Headache, Overall (N=4372,4376)	157	30		
Related Headache, Overall (N=4372,4376)	1470	469		
Any Myalgia, Overall (N=4372,4376)	2023	529		
Grade 3 Myalgia, Overall (N=4372,4376)	236	31		
Related Myalgia, Overall (N=4372,4376)	1791	390		
Any Shivering, Overall (N=4372,4376)	1232	259		
Grade 3 Shivering, Overall (N=4372,4376)	192	11		
Related Shivering, Overall (N=4372,4376)	1082	177		
Any Temperature, Overall (N=4372,4376)	940	132		
Grade 3 Temperature, Overall (N=4372,4376)	14	6		
Related Temperature, Overall (N=4372,4376)	813	78		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any and Grade 3 symptoms (solicited and unsolicited)

End point title	Number of subjects with any and Grade 3 symptoms (solicited and unsolicited)
End point description:	Number of subjects with any and grade 3 solicited and unsolicited symptoms were tabulated.
End point type	Secondary

End point timeframe:

Within the 7-day (Days 0-6) post-vaccination period

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4457	4464		
Units: Subjects				
Any solicited or unsolicited symptoms	3766	1691		
Grade 3 solicited or unsolicited symptoms	759	145		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any and related potential Immune mediated diseases (pIMDs)

End point title: Number of subjects with any and related potential Immune mediated diseases (pIMDs)

End point description:

Occurrence and relationship to vaccination of any potential immune-mediated diseases (pIMDs) in all subjects

End point type: Secondary

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7695	7710		
Units: Subjects				
Any pIMDs	87	105		
Related pIMDs	8	12		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with AEs with any and related medically attended visit (MAEs)

End point title: Number of subjects with AEs with any and related medically attended visit (MAEs)

End point description:

Occurrence and relationship to vaccination of medically attended visits (defined as hospitalizations, emergency room visits or visits to or from medical personnel), other than routine health care visits in all subjects.

End point type Secondary

End point timeframe:

From Month 0 to Month 8 post-vaccination

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7695	7710		
Units: Subjects				
Any MAEs	2952	3072		
Related MAEs	142	60		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title Number of subjects with unsolicited adverse events (AEs)

End point description:

Occurrence, intensity and relationship to vaccination of unsolicited AEs, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects. An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type Secondary

End point timeframe:

Within 30 days (Days 0 - 29) after each vaccination

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7695	7710		
Units: Subjects				
Any AEs	3534	2426		
Grade 3 AEs	609	298		
Related AEs	2199	439		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)
-----------------	---

End point description:

Occurrence and relationship to vaccination of all SAEs in all subjects. Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

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

End point timeframe:

Within the 30-day (Days 0-29) post-vaccination period, up to Month 14 and up to study end (3 to 5 year period following Day 0)

End point values	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7695	7710		
Units: Subjects				
Any SAEs (up to Day 30)	88	97		
Related SAEs (up to Day 30)	1	3		
Any SAEs (up to Month 14)	594	590		
Related SAEs (up to Month 14)	3	6		
Any SAEs (up to study end)	727	731		
Related SAEs (up to study end)	3	7		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with SAEs related to study participation or to a concurrent GSK medication/vaccine

End point title	Number of subjects with SAEs related to study participation or to a concurrent GSK medication/vaccine
-----------------	---

End point description:

The number of subjects with SAEs related to study participation or to a concurrent GSK medication/vaccine were tabulated.

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

End point timeframe:

During the entire study period (3 to 5 year period following Day 0).

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7695	7710		
Units: Subjects	43	25		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with fatal SAEs

End point title	Number of subjects with fatal SAEs
End point description:	Number of subjects with fatal SAEs during the entire study period were tabulated.
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 years following day 0).

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7695	7710		
Units: Subjects	208	221		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: within 7 days post-vaccination  
 Unsolicited AEs: within 30 days post vaccination  
 SAEs: during the entire study period (3 to 5 year period following Day 0)

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

### Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

### Reporting groups

Reporting group title	GSK1437173A Group
-----------------------	-------------------

Reporting group description:

Subjects received herpes zoster subunit vaccine (gE/AS01B vaccine: GSK1437173A) according to a 0, 2-month schedule.

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

Reporting group description:

Subjects received saline solution (NaCl solution) as control according to a 0, 2-month schedule.

<b>Serious adverse events</b>	GSK1437173A Group	Placebo Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	727 / 7695 (9.45%)	731 / 7710 (9.48%)	
number of deaths (all causes)	11	15	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute leukaemia			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Acute promyelocytic leukaemia			

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Adenocarcinoma gastric		
subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Angioimmunoblastic t-cell lymphoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Basal cell carcinoma		
subjects affected / exposed	4 / 7695 (0.05%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adult t-cell lymphoma/leukaemia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Benign neoplasm of thyroid gland		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 orbit		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign renal neoplasm		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct adenocarcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign soft tissue neoplasm		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct cancer		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Bladder cancer		
subjects affected / exposed	3 / 7695 (0.04%)	5 / 7710 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Bladder neoplasm		

subjects affected / exposed	0 / 7695 (0.00%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Brain neoplasm</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Bowen's disease</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain cancer metastatic</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast cancer</b>		
subjects affected / exposed	8 / 7695 (0.10%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast cancer female</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain neoplasm malignant</b>		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Breast cancer in situ</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer metastatic</b>		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Bronchial carcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Bronchial neoplasm		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cervix carcinoma recurrent		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour of the small bowel		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		

subjects affected / exposed	3 / 7695 (0.04%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 3
Colon adenoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	7 / 7695 (0.09%)	11 / 7710 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 2	0 / 5
Diffuse large b-cell lymphoma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extranodal marginal zone b-cell lymphoma (malt type)		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fallopian tube cancer		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cancer		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Gastrointestinal neoplasm		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric cancer		
subjects affected / exposed	4 / 7695 (0.05%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 1
Glioblastoma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Glioblastoma multiforme		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal stromal tumour		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioma		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Glomus tumour		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic cancer		

subjects affected / exposed	4 / 7695 (0.05%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1
Hepatic neoplasm		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Hypopharyngeal cancer		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	3 / 7695 (0.04%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	5 / 7695 (0.06%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Invasive papillary breast carcinoma		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal neoplasm		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Leukaemia		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lip and/or oral cavity cancer		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lip squamous cell carcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	4 / 7695 (0.05%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Lung adenocarcinoma metastatic		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Lung adenocarcinoma stage i		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		

subjects affected / exposed	11 / 7695 (0.14%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 9	0 / 3
Lung neoplasm		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung cancer metastatic		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Lymphoma		
subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Malignant melanoma		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of pleura metastatic		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant neoplasm of unknown primary site		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Melanocytic naevus		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Malignant pleural effusion</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metastases to liver</b>			
subjects affected / exposed	3 / 7695 (0.04%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
<b>Metastases to lung</b>			
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
<b>Metastases to central nervous system</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Metastases to lymph</b>			
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metastases to peritoneum</b>			
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
<b>Metastases to pleura</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Metastasis</b>			

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic carcinoma of the bladder		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic squamous cell carcinoma		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic neoplasm		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Nasopharyngeal cancer		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Neoplasm skin		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal adenocarcinoma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Non-small cell lung cancer		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Neuroendocrine carcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ovarian fibroma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Oesophageal squamous cell carcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	6 / 7695 (0.08%)	8 / 7710 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 5	0 / 8
Pancreatic carcinoma metastatic		

subjects affected / exposed	3 / 7695 (0.04%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 1
Pancreatic neoplasm		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian neoplasm		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pheochromocytoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	3 / 7695 (0.04%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Pleural mesothelioma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Prostate cancer recurrent		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0
Prostate cancer		

subjects affected / exposed	7 / 7695 (0.09%)	9 / 7710 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Prostatic adenoma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Rectal adenoma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cancer		
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer metastatic		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal neoplasm		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal oncocytoma		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Small intestine adenocarcinoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Spinal cord neoplasm		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 of lung		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Squamous cell carcinoma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 of skin		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 9	0 / 1
Thyroid adenoma		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular neoplasm		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid neoplasm		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tumour haemorrhage		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine cancer		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Uterine leiomyoma		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval cancer		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Vascular disorders</b>			
<b>Aneurysm</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Angiodysplasia</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic dilatation</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic aneurysm</b>			
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic dissection</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic rupture</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Aortic stenosis</b>			
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arterial thrombosis</b>			

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial disorder		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Circulatory collapse		
subjects affected / exposed	2 / 7695 (0.03%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2
Arteriosclerosis		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bleeding varicose vein		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Deep vein thrombosis		
subjects affected / exposed	3 / 7695 (0.04%)	5 / 7710 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic vascular disorder		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Essential hypertension		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		

subjects affected / exposed	8 / 7695 (0.10%)	10 / 7710 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemorrhage</b>		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma</b>		
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemodynamic instability</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Hypertensive emergency</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypotension</b>		
subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive crisis</b>		
subjects affected / exposed	2 / 7695 (0.03%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orthostatic hypertension</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypovolaemic shock</b>		

subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 3
Intermittent claudication		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	2 / 7695 (0.03%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Orthostatic hypotension		
subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		

subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Superior vena cava syndrome			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Shock haemorrhagic			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarteritis nodosa			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (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	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Surgical and medical procedures</b>			
Cardiac pacemaker replacement			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>General disorders and administration site conditions</b>			
Asthenia			
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	12 / 7695 (0.16%)	10 / 7710 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	11 / 7695 (0.14%)	15 / 7710 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 11	0 / 15	
Device dislocation			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

Drowning			
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Drug withdrawal syndrome			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gravitational oedema			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza like illness			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			

subjects affected / exposed	6 / 7695 (0.08%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 6	0 / 2
Non-cardiac chest pain		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyp		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Strangulated hernia		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden death		
subjects affected / exposed	5 / 7695 (0.06%)	7 / 7710 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 5	0 / 7
Sudden cardiac death		

subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
<b>Systemic inflammatory response syndrome</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Immune system disorders</b>			
<b>Anaphylactic reaction</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Drug hypersensitivity</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypersensitivity</b>			
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sarcoidosis</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	3 / 7695 (0.04%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cystocele</b>			
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Endometrial hypertrophy			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrocystic breast disease			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine enlargement			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	2 / 7695 (0.03%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 2	
Acute pulmonary oedema			
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aspiration			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchitis chronic			
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	6 / 7695 (0.08%)	5 / 7710 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	8 / 7695 (0.10%)	8 / 7710 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 4
Emphysema		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Epistaxis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Nasal polyps		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paranasal cyst		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	3 / 7695 (0.04%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Pleural calcification		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pickwickian syndrome		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		

subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3
Pneumothorax		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary bulla		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	6 / 7695 (0.08%)	13 / 7710 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 4	0 / 4
Pulmonary fibrosis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary oedema		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Respiratory acidosis		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Respiratory failure</b>			
subjects affected / exposed	7 / 7695 (0.09%)	12 / 7710 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 5	0 / 8	
<b>Sleep apnoea syndrome</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory distress</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Psychiatric disorders</b>			
<b>Abnormal behaviour</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Completed suicide</b>			
subjects affected / exposed	4 / 7695 (0.05%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 4	0 / 4	
<b>Delirium</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Adjustment disorder</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Delirium febrile</b>			

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised anxiety disorder		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Korsakoff's syndrome		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	3 / 7695 (0.04%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Suicidal ideation		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Somatoform disorder		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psychotic disorder		
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	4 / 7695 (0.05%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood heavy metal increased			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Acetabulum fracture			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Aneurysm perforation			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Burns second degree			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	7 / 7695 (0.09%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns third degree			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation complication			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical poisoning			
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Electrical burn		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye penetration		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	5 / 7695 (0.06%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		

subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Femur fracture		
subjects affected / exposed	7 / 7695 (0.09%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Flail chest		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gun shot wound		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Fractured sacrum		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		

subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (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	3 / 7695 (0.04%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Hip fracture		
subjects affected / exposed	2 / 7695 (0.03%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Joint dislocation		

subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle strain</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple injuries</b>		
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Overdose</b>		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Open fracture</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nerve root injury cervical</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Patella fracture</b>		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax traumatic</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic fracture</b>		

subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	7 / 7695 (0.09%)	7 / 7710 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory fume inhalation disorder		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pubis fracture		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		

subjects affected / exposed	1 / 7695 (0.01%)	5 / 7710 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 3
<b>Seroma</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Snake bite</b>		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skull fracture</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Skin abrasion</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal compression fracture</b>		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal cord injury</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Soft tissue injury</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal fracture</b>		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Sternal fracture		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Spinal cord injury cervical		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Subdural haemorrhage		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Tibia fracture		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Traumatic intracranial haemorrhage		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Traumatic shock		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Upper limb fracture		
subjects affected / exposed	4 / 7695 (0.05%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm ruptured		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Cystic fibrosis			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hernia congenital			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	4 / 7695 (0.05%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	3 / 7695 (0.04%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	8 / 7695 (0.10%)	19 / 7710 (0.25%)	
occurrences causally related to treatment / all	0 / 8	0 / 19	
deaths causally related to treatment / all	0 / 3	0 / 10	

Angina unstable			
subjects affected / exposed	2 / 7695 (0.03%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	6 / 7695 (0.08%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial fibrillation			
subjects affected / exposed	19 / 7695 (0.25%)	6 / 7710 (0.08%)	
occurrences causally related to treatment / all	0 / 23	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 0	
Atrial flutter			
subjects affected / exposed	4 / 7695 (0.05%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial tachycardia			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrioventricular block second degree			

subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	8 / 7695 (0.10%)	8 / 7710 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 7	0 / 6
Cardiac failure		
subjects affected / exposed	20 / 7695 (0.26%)	24 / 7710 (0.31%)
occurrences causally related to treatment / all	0 / 21	0 / 27
deaths causally related to treatment / all	0 / 11	0 / 15
Cardiac failure acute		
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Cardiac failure congestive		
subjects affected / exposed	14 / 7695 (0.18%)	10 / 7710 (0.13%)
occurrences causally related to treatment / all	0 / 15	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 3
Cardiac failure chronic		

subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac valve disease		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Cardiomyopathy alcoholic		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiovascular deconditioning		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cor pulmonale		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery disease		
subjects affected / exposed	11 / 7695 (0.14%)	17 / 7710 (0.22%)
occurrences causally related to treatment / all	0 / 11	0 / 19
deaths causally related to treatment / all	0 / 1	0 / 2
Coronary artery occlusion		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	4 / 7695 (0.05%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac thrombus		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve prolapse		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Mitral valve stenosis		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial infarction</b>		
subjects affected / exposed	28 / 7695 (0.36%)	27 / 7710 (0.35%)
occurrences causally related to treatment / all	0 / 28	0 / 27
deaths causally related to treatment / all	0 / 15	0 / 13
<b>Myocardial ischaemia</b>		
subjects affected / exposed	7 / 7695 (0.09%)	11 / 7710 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 4
<b>Palpitations</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial effusion</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pericarditis</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Right ventricular failure</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus node dysfunction</b>		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stress cardiomyopathy</b>		

subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ventricular tachycardia			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Odontogenic cyst			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Aphasia			

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal ganglia haemorrhage		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Amyotrophic lateral sclerosis		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Basal ganglia infarction		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain injury		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery thrombosis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		

subjects affected / exposed	2 / 7695 (0.03%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 4
Cerebral infarction		
subjects affected / exposed	8 / 7695 (0.10%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 3
Cerebral ischaemia		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebrovascular accident		
subjects affected / exposed	19 / 7695 (0.25%)	12 / 7710 (0.16%)
occurrences causally related to treatment / all	0 / 19	0 / 12
deaths causally related to treatment / all	0 / 8	0 / 6
Cerebrovascular disorder		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia alzheimer's type		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Coma		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelinating polyneuropathy		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	3 / 7695 (0.04%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhage intracranial</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemorrhagic transformation stroke</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Headache</b>		
subjects affected / exposed	4 / 7695 (0.05%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hemiparesis</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoaesthesia</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydrocephalus</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intracranial aneurysm</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic stroke</b>		

subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ivth nerve paralysis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar infarction		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Mononeuritis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelopathy</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nerve compression</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nervous system disorder</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuritis cranial</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paraneoplastic neurological syndrome</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paraesthesia</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Presyncope</b>		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post polio syndrome</b>		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sciatica</b>		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Radiculopathy</b>		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Reversible ischaemic neurological deficit</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ruptured cerebral aneurysm</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Spinal claudication</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subarachnoid haemorrhage</b>		
subjects affected / exposed	2 / 7695 (0.03%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Syncope</b>		
subjects affected / exposed	8 / 7695 (0.10%)	8 / 7710 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Seizure</b>		

subjects affected / exposed	3 / 7695 (0.04%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	8 / 7695 (0.10%)	6 / 7710 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis cerebral			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viith nerve paralysis			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 7695 (0.08%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Disseminated intravascular coagulation			

subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Anaemia vitamin b12 deficiency		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic haemorrhage			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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			
Motion sickness			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	4 / 7695 (0.05%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Amaurosis fugax			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	2 / 7695 (0.03%)	5 / 7710 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens dislocation			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular cyst			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	1 / 7695 (0.01%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous detachment			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal strangulated hernia			

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Colitis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	4 / 7695 (0.05%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Diverticulum intestinal		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Functional gastrointestinal disorder		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric mucosal lesion		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	3 / 7695 (0.04%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	5 / 7695 (0.06%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis alcoholic		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	3 / 7695 (0.04%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Gastrointestinal polyp haemorrhage		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroesophageal reflux disease</b>		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhoidal haemorrhage</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gingival disorder</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhoids</b>		
subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hiatus hernia</b>		
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus</b>		
subjects affected / exposed	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Inguinal hernia</b>		
subjects affected / exposed	3 / 7695 (0.04%)	8 / 7710 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incarcerated umbilical hernia</b>		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal congestion		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	3 / 7695 (0.04%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Intestinal polyp		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-weiss syndrome		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal ulcer		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophagitis		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic fistula		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	4 / 7695 (0.05%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	5 / 7695 (0.06%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis necrotising		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontal disease		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer perforation		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal cyst		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal haemorrhage		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumoperitoneum		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Portal hypertensive gastropathy		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal polyp</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retroperitoneal haemorrhage</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Small intestinal obstruction</b>		
subjects affected / exposed	2 / 7695 (0.03%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splenic artery aneurysm</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subileus</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thrombosis mesenteric vessel</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Upper gastrointestinal haemorrhage</b>		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Volvulus</b>		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vomiting			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	5 / 7695 (0.06%)	6 / 7710 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	7 / 7695 (0.09%)	10 / 7710 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	6 / 7695 (0.08%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Fatty liver alcoholic		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gallbladder polyp		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Hepatic cirrhosis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatotoxicity		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Biliary dyskinesia</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin and subcutaneous tissue disorders</b>			
<b>Decubitus ulcer</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Eczema</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dermal cyst</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dermatitis</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic foot</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Erythema multiforme</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Leukoplakia</b>			

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psoriasis</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperkeratosis</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin ulcer</b>			
subjects affected / exposed	4 / 7695 (0.05%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>Azotaemia</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Acute kidney injury</b>			
subjects affected / exposed	8 / 7695 (0.10%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 6	0 / 1	
<b>Bladder prolapse</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Calculus urinary</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Chronic kidney disease</b>			

subjects affected / exposed	2 / 7695 (0.03%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 4
Calculus bladder		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus ureteric		
subjects affected / exposed	4 / 7695 (0.05%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery arteriosclerosis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery occlusion		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Renal impairment		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral polyp		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		

subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endocrine disorders</b>			
<b>Goitre</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Basedow's disease</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypopituitarism</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thyroiditis subacute</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthropathy</b>			
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Back pain</b>			
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Costochondritis			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fasciitis			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 7695 (0.01%)	7 / 7710 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint destruction			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	0 / 7695 (0.00%)	1 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	8 / 7695 (0.10%)	11 / 7710 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteolysis		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	4 / 7695 (0.05%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue mass		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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	1 / 7695 (0.01%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal disorder		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Still's disease adult onset		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	3 / 7695 (0.04%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendonitis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic lupus erythematosus		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal infection</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal sepsis</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Abscess neck</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abscess</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anal abscess</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Appendiceal abscess</b>			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Appendicitis perforated</b>			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Appendicitis</b>			

subjects affected / exposed	3 / 7695 (0.04%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atypical pneumonia</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteraemia</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteriuria</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial infection</b>		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast abscess</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Biliary sepsis</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis bacterial</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		

subjects affected / exposed	3 / 7695 (0.04%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Candiduria		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopneumonia		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Catheter site infection		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	8 / 7695 (0.10%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis orbital		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis streptococcal		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (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	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		

subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Dengue fever		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis klebsiella		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	4 / 7695 (0.05%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 2
Encephalomyelitis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		

subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Endometritis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	2 / 7695 (0.03%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Fungaemia		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis caliciviral		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	3 / 7695 (0.04%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Gastroenteritis salmonella		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Helicobacter gastritis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis a		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Infected dermal cyst		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Klebsiella sepsis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Labyrinthitis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leptospirosis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lobar pneumonia		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		

subjects affected / exposed	1 / 7695 (0.01%)	6 / 7710 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
Localised infection		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymph node tuberculosis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Meningitis pneumococcal		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal abscess		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mycobacterial infection		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Neuroborreliosis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngitis		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Osteomyelitis</b>		
subjects affected / exposed	4 / 7695 (0.05%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis chronic</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritonitis</b>		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Otitis media chronic</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periodontitis</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritonsillar abscess</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pertussis</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pharyngitis</b>		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngotonsillitis		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia		
subjects affected / exposed	40 / 7695 (0.52%)	26 / 7710 (0.34%)
occurrences causally related to treatment / all	0 / 41	0 / 28
deaths causally related to treatment / all	0 / 15	0 / 9
Pneumonia bacterial		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia mycoplasmal		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	0 / 7695 (0.00%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pyelonephritis acute		

subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory tract infection</b>		
subjects affected / exposed	3 / 7695 (0.04%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis</b>		
subjects affected / exposed	6 / 7695 (0.08%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Sepsis</b>		
subjects affected / exposed	7 / 7695 (0.09%)	13 / 7710 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 14
deaths causally related to treatment / all	0 / 5	0 / 9
<b>Septic shock</b>		
subjects affected / exposed	1 / 7695 (0.01%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Shigella infection</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinusitis</b>		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Serratia infection</b>		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Sinusitis fungal</b>		

subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Subcutaneous abscess		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdiaphragmatic abscess		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Superinfection		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular abscess		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic shock syndrome		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tularaemia		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection bacterial		
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethritis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	2 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	2 / 7695 (0.03%)	3 / 7710 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Urinary tract infection		
subjects affected / exposed	10 / 7695 (0.13%)	10 / 7710 (0.13%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 1
Vestibular neuronitis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral sepsis			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visceral leishmaniasis			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 7695 (0.03%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection pseudomonas			
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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			
Decreased appetite			
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	4 / 7695 (0.05%)	2 / 7710 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetes mellitus			

subjects affected / exposed	3 / 7695 (0.04%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetes mellitus inadequate control		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperammonaemia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 7695 (0.01%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	1 / 7695 (0.01%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hypertriglyceridaemia		

subjects affected / exposed	1 / 7695 (0.01%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperlipidaemia		
subjects affected / exposed	3 / 7695 (0.04%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	2 / 7695 (0.03%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	3 / 7695 (0.04%)	0 / 7710 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ketoacidosis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (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 / 7695 (0.03%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Type 1 diabetes mellitus		
subjects affected / exposed	0 / 7695 (0.00%)	2 / 7710 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		

subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	0 / 7695 (0.00%)	1 / 7710 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Type 2 diabetes mellitus		
subjects affected / exposed	2 / 7695 (0.03%)	4 / 7710 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	GSK1437173A Group	Placebo Group
Total subjects affected by non-serious adverse events		
subjects affected / exposed	5586 / 7695 (72.59%)	1893 / 7710 (24.55%)
Nervous system disorders		
Headache		
subjects affected / exposed	2167 / 7695 (28.16%)	929 / 7710 (12.05%)
occurrences (all)	3044	1198
General disorders and administration site conditions		
Chills		
subjects affected / exposed	1464 / 7695 (19.03%)	276 / 7710 (3.58%)
occurrences (all)	1860	314
Injection site erythema		
subjects affected / exposed	493 / 7695 (6.41%)	10 / 7710 (0.13%)
occurrences (all)	636	11
Fatigue		
subjects affected / exposed	2211 / 7695 (28.73%)	770 / 7710 (9.99%)
occurrences (all)	3111	961
Injection site pain		

subjects affected / exposed	1390 / 7695 (18.06%)	104 / 7710 (1.35%)	
occurrences (all)	2090	118	
Injection site swelling			
subjects affected / exposed	401 / 7695 (5.21%)	6 / 7710 (0.08%)	
occurrences (all)	515	6	
Swelling			
subjects affected / exposed	1154 / 7695 (15.00%)	46 / 7710 (0.60%)	
occurrences (all)	1573	48	
Pyrexia			
subjects affected / exposed	1498 / 7695 (19.47%)	168 / 7710 (2.18%)	
occurrences (all)	1839	176	
Pain			
subjects affected / exposed	3575 / 7695 (46.46%)	505 / 7710 (6.55%)	
occurrences (all)	6064	627	
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	792 / 7695 (10.29%)	389 / 7710 (5.05%)	
occurrences (all)	967	449	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1690 / 7695 (21.96%)	69 / 7710 (0.89%)	
occurrences (all)	2408	75	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	2277 / 7695 (29.59%)	571 / 7710 (7.41%)	
occurrences (all)	3234	704	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 April 2014	<p>It is predicted that study ZOSTER-006 will reach the conditions required for triggering final analysis of herpes zoster (HZ) primary endpoint about one year before those conditions being reached for study ZOSTER-022. Therefore GSK decided, as originally planned in these circumstances, to dissociate the two studies in terms of timing of the analysis of each study. Moreover, a two-step approach is allowed for the analysis of each study. Both studies will end concurrently .</p> <p>In study ZOSTER-022, postherpetic neuralgia (PHN) is demoted from co-primary endpoint to a descriptive secondary endpoint and the overall PHN co-primary endpoint in subjects <math>\geq 70</math> YOA for pooled analyses of ZOSTER 006 and ZOSTER-022 will be considered as primary analysis for PHN. Overall PHN in subjects <math>\geq 50</math> YOA has become a secondary endpoint for pooled analyses of ZOSTER-006 and ZOSTER-022. The applicable objectives and endpoints have been updated accordingly in the ZOSTER-022 protocol. Pooled analyses of ZOSTER-006 and ZOSTER-022 will only be conducted if the primary objective [HZ vaccine efficacy (VE)] is demonstrated in both ZOSTER-006 and ZOSTER-022 separately.</p> <p>Regarding the reporting of SAEs that are related to study participation (e.g. protocol-mandated procedures, invasive tests, a change from existing therapy) or are related to a concurrent GSK medication/vaccine or any fatal SAE, it has been clarified that this includes SAEs that are considered by the investigator to be related to the investigational vaccine and are to be reported until study end.</p>

Notes:

---

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported