



## Clinical trial results:

**A Phase IIIB, non-randomized, open-label, multicountry, multi-centric cross-vaccination study to evaluate the safety of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine when administered intramuscularly on a two-dose schedule to subjects who previously received placebo in ZOSTER-006 and ZOSTER-022 studies.**

### Summary

EudraCT number	2015-000965-30
Trial protocol	FI EE CZ GB DE ES FR IT
Global end of trial date	15 March 2019

### Results information

Result version number	v1 (current)
This version publication date	13 March 2020
First version publication date	13 March 2020

### Trial information

#### Trial identification

Sponsor protocol code	204486
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02690207
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	27 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2019
Global end of trial reached?	Yes
Global end of trial date	15 March 2019
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the safety, in terms of unsolicited Adverse Events (AEs), Serious Adverse Events (SAE) and potential Immune Mediated Disease (pIMD) in all subjects, following administration of each dose of the HZ/su vaccine.

Protection of trial subjects:

The subjects were observed closely for at least 30 minutes following the administration of the vaccines, with appropriate medical treatment readily available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 March 2016
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: 196
Country: Number of subjects enrolled	Brazil: 356
Country: Number of subjects enrolled	Canada: 486
Country: Number of subjects enrolled	Czech Republic: 442
Country: Number of subjects enrolled	Estonia: 786
Country: Number of subjects enrolled	Finland: 1132
Country: Number of subjects enrolled	France: 327
Country: Number of subjects enrolled	Germany: 529
Country: Number of subjects enrolled	Hong Kong: 223
Country: Number of subjects enrolled	Italy: 85
Country: Number of subjects enrolled	Japan: 220
Country: Number of subjects enrolled	Korea, Republic of: 312
Country: Number of subjects enrolled	Mexico: 610
Country: Number of subjects enrolled	Spain: 490
Country: Number of subjects enrolled	Sweden: 684
Country: Number of subjects enrolled	Taiwan: 674
Country: Number of subjects enrolled	United Kingdom: 331
Country: Number of subjects enrolled	United States: 804
Worldwide total number of subjects	8687
EEA total number of subjects	4806

Notes:

<b>Subjects enrolled per age group</b>	
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)	2326
From 65 to 84 years	5574
85 years and over	787

## Subject disposition

### Recruitment

Recruitment details:

Potentially eligible subjects who received placebo in ZOSTER-006 (NCT01165177) and ZOSTER-022 (NCT01165229) studies were enrolled in this study.

### Pre-assignment

Screening details:

8687 subjects were enrolled in this study and received Herpes Zoster sub-unit vaccine. Of these, 8434 subjects completed the trial and 253 subjects withdrew.

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

This is not applicable as there was no blinding in this study (open-label)

### Arms

<b>Arm title</b>	HZ/su Group
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Arm description:

Subjects received Herpes Zoster subunit vaccine, administered intramuscularly (IM) in the deltoid of the non-dominant arm

Arm type	Experimental
Investigational medicinal product name	HZ/su Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses of vaccine (0.5 mL each) were administered according to a 0,2-month vaccination schedule.

<b>Number of subjects in period 1</b>	HZ/su Group
Started	8687
Completed	8434
Not completed	253
Consent withdrawn by subject	46
Migrated/moved from study area	5
Other reasons for withdrawal	23
Suspected HZ Episode	1
Serious adverse event	110
Lost to follow-up	48
Non-serious Adverse Event	18
Protocol deviation	2



## Baseline characteristics

### Reporting groups

Reporting group title	HZ/su Group
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Reporting group description:

Subjects received Herpes Zoster subunit vaccine, administered intramuscularly (IM) in the deltoid of the non-dominant arm

Reporting group values	HZ/su Group	Total	
Number of subjects	8687	8687	
Age Categorical			
Units: Participants			
Age 18-64 years	2326	2326	
Age 65-84 years	5574	5574	
Age 85 years and over	787	787	
Age continuous			
Units: years			
arithmetic mean	72.6		
standard deviation	± 9.4	-	
Sex/Gender, Customized			
Units: Participants			
Female	5254	5254	
Male	3433	3433	
Race/Ethnicity, Customized			
Units: Subjects			
African Heritage/ African American	72	72	
American Indian or Alaskan Native	7	7	
Asian-Central/South Asian Heritage	5	5	
Asian-East Asian Heritage	1202	1202	
Asian-Japanese Heritage	254	254	
Asian-South East Asian Heritage	12	12	
Native Hawaiian or Other Pacific Islander	3	3	
White-Arabic/North African Heritage	47	47	
White-Caucasian / European Heritage	6361	6361	
Mixed origin	724	724	

## End points

### End points reporting groups

Reporting group title	HZ/su Group
Reporting group description: Subjects received Herpes Zoster subunit vaccine, administered intramuscularly (IM) in the deltoid of the non-dominant arm	

### Primary: Number of subjects with Any, Grade 3 and Related Unsolicited Adverse Events (AEs)

End point title	Number of subjects with Any, Grade 3 and Related Unsolicited Adverse Events (AEs) <sup>[1]</sup>
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End point description:

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. 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.

This analysis was performed on Total vaccinated cohort, which included all subjects with at least one HZ/su vaccine administration documented for whom data were available

End point type	Primary
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End point timeframe:

During 30 days (Days 0-29) after any vaccination (across doses)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive, hence no statistical analyses were available.

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	8687			
Units: Subjects				
Any AE(s)	5175			
Grade 3 AE(s)	963			
Related AE(s)	4422			

### Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with Any and Related Serious Adverse Events (SAEs)

End point title	Number of subjects with Any and Related Serious Adverse Events (SAEs) <sup>[2]</sup>
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End point description:

Serious adverse events (SAEs) assessed include medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity. Related=SAE assessed by the investigator as related to the vaccination.

This analysis was performed on Total vaccinated cohort, which included all subjects with at least one HZ/su vaccine administration documented for whom data were available

End point type	Primary
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End point timeframe:

From Month 0 until study end (Month 14, i.e. 12 months post dose 2)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive, hence no statistical analyses were available.

<b>End point values</b>	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	8687			
Units: Subjects				
Any SAE(s)	734			
Related SAE(s)	2			

### Statistical analyses

No statistical analyses for this end point

### Primary: 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) <sup>[3]</sup>
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End point description:

pIMDs are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune aetiology. Related pIMDs=pIMDs assessed by the investigator as related to the vaccination.

This analysis was performed on Total vaccinated cohort, which included all subjects with at least one HZ/su vaccine administration documented for whom data were available

End point type	Primary
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End point timeframe:

From Month 0 until study end (Month 14, i.e. 12 months post dose 2)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive, hence no statistical analyses were available.

<b>End point values</b>	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	8687			
Units: Subjects				
Any pIMD(s)	62			
Related pIMD(s)	1			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with at least one suspected Herpes Zoster (HZ) case

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End point title	Number of subjects with at least one suspected Herpes Zoster (HZ) case(s)
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End point description:

A suspected case of HZ was defined as a new rash characteristic of HZ (e.g., unilateral, dermatomal and accompanied by pain broadly defined to include allodynia, pruritus or other sensations).

Clinically confirmed HZ episode is suspected HZ episode confirmed by the Investigator/Delegate

This analysis was performed on Total vaccinated cohort, which included all subjects with at least one HZ/su vaccine administration documented for whom data were available

End point type	Secondary
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End point timeframe:

From Month 0 until study end (Month 14, i.e. 12 months post dose 2)

<b>End point values</b>	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	8687			
Units: Subjects				
HZ episode	30			
Suspected HZ episode only	8			
Clinically confirmed HZ episode	22			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Unsolicited AEs were collected during the 30 days (Days 0-29) follow-up period after any vaccination (across doses). SAEs were collected from Month 0 until study end (Month 14, i.e. 12 months post dose 2).

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

### Reporting groups

Reporting group title	HZ/su Group
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Reporting group description:

Subjects received herpes zoster subunit vaccine, administered intramuscularly (IM) in the deltoid of the non-dominant arm

Serious adverse events	HZ/su Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	734 / 8687 (8.45%)		
number of deaths (all causes)	107		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma pancreas			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>B precursor type acute leukaemia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Basal cell carcinoma</b>			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
<b>Benign lung neoplasm</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bladder cancer</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bladder neoplasm</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bladder transitional cell carcinoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Brain neoplasm</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Breast cancer</b>			

subjects affected / exposed	12 / 8687 (0.14%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
<b>Cancer pain</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cardiac myxoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cholangiocarcinoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Chronic lymphocytic leukaemia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Chronic myeloid leukaemia</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Colon adenoma</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Colon cancer</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
<b>Colon cancer metastatic</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon neoplasm			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colorectal cancer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ganglioneuroma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Gastric neoplasm			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal neoplasm			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Glioblastoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Glioblastoma multiforme</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Hepatocellular carcinoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Hodgkin's disease</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hypopharyngeal neoplasm</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Insulinoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Invasive breast carcinoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Invasive ductal breast carcinoma</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestine benign neoplasm			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laryngeal cancer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm malignant			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 4		
Malignant melanoma in situ			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Marginal zone lymphoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to lung			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastatic malignant melanoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metastatic neoplasm			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal carcinoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer recurrent			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Penile cancer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Prostate cancer			
subjects affected / exposed	9 / 8687 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Rectal adenocarcinoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal neoplasm			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cancer			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Renal cell carcinoma recurrent			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Salivary gland neoplasm			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			

subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Uterine cancer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Aortic dissection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic rupture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic stenosis			

subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Arterial rupture</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Arteriosclerosis</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Deep vein thrombosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Embolism venous</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Extremity necrosis</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Haematoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hypertension</b>			
subjects affected / exposed	10 / 8687 (0.12%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
<b>Hypertensive crisis</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Intermittent claudication			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Peripheral venous disease			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Phlebitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Poor peripheral circulation			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Shock haemorrhagic			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subclavian steal syndrome			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Temporal arteritis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Accidental death			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Adverse drug reaction			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 6		
General physical health deterioration			

subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Oedema			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Pyrexia			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Vascular stent stenosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular stent thrombosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Drug hypersensitivity</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hypersensitivity</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Reproductive system and breast disorders</b>			
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Breast pain</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cystocele</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Erectile dysfunction</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Menorrhagia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Ovarian cyst</b>			

subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Prostatitis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Rectocele</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>Acute pulmonary oedema</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
<b>Acute respiratory distress syndrome</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Acute respiratory failure</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Asthma</b>			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Atelectasis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Chronic obstructive pulmonary disease</b>			

subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 2		
<b>Dyspnoea</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
<b>Haemoptysis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haemothorax</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Interstitial lung disease</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Lung disorder</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pleural effusion</b>			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 3		
<b>Pneumonia aspiration</b>			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
<b>Pneumothorax</b>			

subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Pneumothorax spontaneous			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 1		
Pulmonary haemorrhage			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary hypertension			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pulmonary oedema			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 2		
Respiratory distress			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory failure			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Sinus perforation			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Psychiatric disorders</b>			
Confusional state			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Investigations</b>			
Blood potassium decreased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Injury, poisoning and procedural complications</b>			
Acetabulum fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		

Anaemia postoperative				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	4 / 8687 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Cardiac valve rupture				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Chest injury				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Concussion				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	4 / 8687 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	3 / 8687 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				

subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 2		
Hip fracture			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Jaw fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kidney contusion			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Ligament rupture</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Limb injury</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Liver contusion</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Lower limb fracture</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Lumbar vertebral fracture</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Multiple fractures</b>			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Multiple injuries</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Patella fracture</b>			

subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Periprosthetic fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Poisoning			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural swelling			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary contusion			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Radiation proctitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Seroma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Shunt occlusion			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Spinal column injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			

subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	7 / 8687 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Transfusion-related acute lung injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Traumatic liver injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulnar nerve injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vascular pseudoaneurysm			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viith nerve injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Left ventricle outflow tract obstruction			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Type v hyperlipidaemia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	18 / 8687 (0.21%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 2		

Angina pectoris				
subjects affected / exposed	12 / 8687 (0.14%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	2 / 8687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	2 / 8687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	2 / 8687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	25 / 8687 (0.29%)			
occurrences causally related to treatment / all	0 / 27			
deaths causally related to treatment / all	0 / 2			
Atrial flutter				
subjects affected / exposed	2 / 8687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Atrial tachycardia				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				

subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block second degree			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bradyarrhythmia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 8		
Cardiac failure			
subjects affected / exposed	28 / 8687 (0.32%)		
occurrences causally related to treatment / all	0 / 32		
deaths causally related to treatment / all	0 / 17		
Cardiac failure acute			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac failure chronic			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			

subjects affected / exposed	14 / 8687 (0.16%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 7		
Cardiac ventricular thrombosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiogenic shock			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiomegaly			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cor pulmonale			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Coronary artery disease			
subjects affected / exposed	9 / 8687 (0.10%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypertensive heart disease			

subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Ischaemic cardiomyopathy</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Mitral valve incompetence</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Mitral valve stenosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Myocardial infarction</b>			
subjects affected / exposed	18 / 8687 (0.21%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 7		
<b>Myocardial ischaemia</b>			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
<b>Myocarditis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Nodal rhythm</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Parasystole</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Pericarditis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prinzmetal angina			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tachyarrhythmia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ventricular tachycardia			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Nervous system disorders</b>			
<b>Basal ganglia haemorrhage</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Carotid artery stenosis</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Carotid sinus syndrome</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cerebellar ataxia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cerebellar infarction</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Cerebral haemorrhage</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 3		
<b>Cerebral infarction</b>			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
<b>Cerebral ischaemia</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	14 / 8687 (0.16%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 3		
Coma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Dizziness			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Embolic cerebral infarction			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Epilepsy			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Facial paralysis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic stroke			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Haemorrhagic transformation stroke			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Lacunar stroke			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Loss of consciousness			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myoclonus			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Neuroglycopenia			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Normal pressure hydrocephalus			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Petit mal epilepsy			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radicular pain			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Transient global amnesia			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Transient ischaemic attack</b>			
subjects affected / exposed	11 / 8687 (0.13%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
<b>Vith nerve paralysis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Senile dementia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Seizure</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
<b>Febrile neutropenia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Immune thrombocytopenic purpura</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Leukocytosis</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Ear and labyrinth disorders</b>			
Acute vestibular syndrome			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Eye disorders</b>			
Cataract			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cataract nuclear			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diplopia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Macular hole			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal artery occlusion			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic gastritis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis ulcerative			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Constipation</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Diarrhoea</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Diverticular perforation</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Diverticulum</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Diverticulum intestinal</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Duodenal ulcer</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Gastric ulcer</b>			
subjects affected / exposed	7 / 8687 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
<b>Gastritis</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal haemorrhage</b>			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 1		
<b>Gastrointestinal inflammation</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Gastrooesophageal reflux disease</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Haematochezia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haemorrhoids</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
<b>Hiatus hernia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Ileus</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Incarcerated umbilical hernia</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Large intestinal obstruction			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Large intestine polyp			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mallory-weiss syndrome			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mouth haemorrhage			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mouth ulceration			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Nausea</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Obstructive pancreatitis</b>			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Oesophageal perforation</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatitis</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatitis acute</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatitis chronic</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Peritoneal haemorrhage</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Small intestinal obstruction</b>			

subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Spigelian hernia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tooth impacted			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Volvulus			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cholecystitis			

subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
<b>Cholecystitis acute</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
<b>Cholelithiasis</b>			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
<b>Hepatic cirrhosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hepatic haematoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Jaundice</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Skin and subcutaneous tissue disorders</b>			
<b>Diabetic foot</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Eczema</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Psoriasis</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Rash pruritic</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Skin ulcer</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Urticaria</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Renal and urinary disorders</b>			
<b>Acute kidney injury</b>			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 1		
<b>Bladder obstruction</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Chronic kidney disease</b>			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 4		
<b>End stage renal disease</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Glomerulonephritis</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haematuria</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
<b>Hydronephrosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Nephrolithiasis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Prerenal failure</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Renal failure</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
<b>Renal impairment</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Renal injury</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Tubulointerstitial nephritis</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Urethral stenosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Ureterolithiasis</b>			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Endocrine disorders</b>			
<b>Goitre</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Toxic goitre</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthralgia</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Arthritis</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Back pain</b>			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		

Gouty arthritis				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemarthrosis				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc compression				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc degeneration				
subjects affected / exposed	2 / 8687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	4 / 8687 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Joint effusion				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	2 / 8687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	1 / 8687 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				

subjects affected / exposed	15 / 8687 (0.17%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
<b>Osteolysis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Osteoporosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Periarthritis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Rhabdomyolysis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Rotator cuff syndrome</b>			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Spinal osteoarthritis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Spinal stenosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Spondylolisthesis</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Tendonitis</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Tenosynovitis stenosans</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Abscess</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Abscess limb</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Appendicitis</b>			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
<b>Appendicitis perforated</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Arthritis bacterial</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Atypical pneumonia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bacterial infection</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Bone tuberculosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bronchitis</b>			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
<b>Cellulitis</b>			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
<b>Clostridium difficile colitis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cytomegalovirus colitis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Diabetic foot infection</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	7 / 8687 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Endophthalmitis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Erysipelas			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Escherichia pyelonephritis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer helicobacter			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			

subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Herpes simplex			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Infectious pleural effusion			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	9 / 8687 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Joint abscess			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver abscess			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Localised infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			

subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
<b>Necrotising fasciitis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Osteomyelitis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Otitis externa</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Paraoesophageal abscess</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pathogen resistance</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Peritonitis</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
<b>Peritonsillar abscess</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pilonidal cyst</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	54 / 8687 (0.62%)		
occurrences causally related to treatment / all	0 / 58		
deaths causally related to treatment / all	0 / 4		
Pneumonia haemophilus			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 1		
Respiratory tract infection bacterial			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			

subjects affected / exposed	10 / 8687 (0.12%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Systemic candida			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Tooth abscess			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	17 / 8687 (0.20%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 1		
Urosepsis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vulval abscess			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinusitis			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Diabetes mellitus inadequate control</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Gout</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Hyperglycaemia</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Hypoglycaemia</b>			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
<b>Hypokalaemia</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hyponatraemia</b>			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
<b>Latent autoimmune diabetes in adults</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Metabolic acidosis</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Tumour lysis syndrome</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Type 1 diabetes mellitus</b>			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Type 2 diabetes mellitus</b>			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	HZ/su Group		
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	5101 / 8687 (58.72%)		
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
<b>Basal cell carcinoma</b>			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
<b>Cholesteatoma</b>			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
<b>Colon adenoma</b>			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Melanocytic naevus			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Seborrhoeic keratosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Skin cancer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Skin papilloma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Squamous cell carcinoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Essential hypertension			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Flushing			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Haematoma			

subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Hot flush subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Hypertension subjects affected / exposed occurrences (all)	20 / 8687 (0.23%) 21		
Hypertensive crisis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Hypotension subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Pallor subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Peripheral venous disease subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Thrombophlebitis subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Thrombophlebitis superficial subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Thrombosis subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Varicose vein subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
General disorders and administration site conditions Administration site discomfort			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Administration site erythema subjects affected / exposed occurrences (all)	20 / 8687 (0.23%) 21		
Administration site oedema subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Administration site pain subjects affected / exposed occurrences (all)	50 / 8687 (0.58%) 57		
Administration site pruritus subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Administration site swelling subjects affected / exposed occurrences (all)	13 / 8687 (0.15%) 13		
Administration site warmth subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Application site burn subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Asthenia subjects affected / exposed occurrences (all)	74 / 8687 (0.85%) 81		
Axillary pain subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Chest discomfort subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Chest pain subjects affected / exposed occurrences (all)	13 / 8687 (0.15%) 14		
Chills			

subjects affected / exposed	319 / 8687 (3.67%)	
occurrences (all)	366	
Cyst		
subjects affected / exposed	1 / 8687 (0.01%)	
occurrences (all)	1	
Discomfort		
subjects affected / exposed	15 / 8687 (0.17%)	
occurrences (all)	16	
Facial pain		
subjects affected / exposed	1 / 8687 (0.01%)	
occurrences (all)	1	
Fatigue		
subjects affected / exposed	384 / 8687 (4.42%)	
occurrences (all)	448	
Feeling abnormal		
subjects affected / exposed	7 / 8687 (0.08%)	
occurrences (all)	7	
Feeling cold		
subjects affected / exposed	47 / 8687 (0.54%)	
occurrences (all)	52	
Feeling hot		
subjects affected / exposed	29 / 8687 (0.33%)	
occurrences (all)	31	
General physical health deterioration		
subjects affected / exposed	7 / 8687 (0.08%)	
occurrences (all)	7	
Hyperthermia		
subjects affected / exposed	2 / 8687 (0.02%)	
occurrences (all)	2	
Inflammation		
subjects affected / exposed	2 / 8687 (0.02%)	
occurrences (all)	2	
Influenza like illness		
subjects affected / exposed	65 / 8687 (0.75%)	
occurrences (all)	74	
Injection site bruising		

subjects affected / exposed occurrences (all)	14 / 8687 (0.16%) 14		
Injection site discomfort subjects affected / exposed occurrences (all)	13 / 8687 (0.15%) 14		
Injection site eczema subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Injection site erythema subjects affected / exposed occurrences (all)	1311 / 8687 (15.09%) 1717		
Injection site exfoliation subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Injection site extravasation subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Injection site haematoma subjects affected / exposed occurrences (all)	13 / 8687 (0.15%) 13		
Injection site haemorrhage subjects affected / exposed occurrences (all)	5 / 8687 (0.06%) 5		
Injection site hyperaesthesia subjects affected / exposed occurrences (all)	7 / 8687 (0.08%) 8		
Injection site hypersensitivity subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Injection site hypertrophy subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Injection site hypoaesthesia subjects affected / exposed occurrences (all)	9 / 8687 (0.10%) 9		

Injection site induration subjects affected / exposed occurrences (all)	64 / 8687 (0.74%) 73		
Injection site inflammation subjects affected / exposed occurrences (all)	85 / 8687 (0.98%) 94		
Injection site irritation subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Injection site joint discomfort subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 2		
Injection site joint pain subjects affected / exposed occurrences (all)	24 / 8687 (0.28%) 25		
Injection site mass subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 7		
Injection site movement impairment subjects affected / exposed occurrences (all)	13 / 8687 (0.15%) 13		
Injection site nodule subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Injection site oedema subjects affected / exposed occurrences (all)	23 / 8687 (0.26%) 24		
Injection site pain subjects affected / exposed occurrences (all)	3173 / 8687 (36.53%) 4579		
Injection site paraesthesia subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Injection site pruritus			

subjects affected / exposed	248 / 8687 (2.85%)		
occurrences (all)	299		
Injection site rash			
subjects affected / exposed	46 / 8687 (0.53%)		
occurrences (all)	51		
Injection site reaction			
subjects affected / exposed	24 / 8687 (0.28%)		
occurrences (all)	27		
Injection site scab			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Injection site swelling			
subjects affected / exposed	928 / 8687 (10.68%)		
occurrences (all)	1194		
Injection site urticaria			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Injection site vesicles			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Injection site warmth			
subjects affected / exposed	177 / 8687 (2.04%)		
occurrences (all)	211		
Malaise			
subjects affected / exposed	226 / 8687 (2.60%)		
occurrences (all)	258		
Nodule			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Oedema peripheral			
subjects affected / exposed	10 / 8687 (0.12%)		
occurrences (all)	10		
Pain			
subjects affected / exposed	183 / 8687 (2.11%)		
occurrences (all)	213		

Peripheral swelling			
subjects affected / exposed	15 / 8687 (0.17%)		
occurrences (all)	16		
Polyp			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	1039 / 8687 (11.96%)		
occurrences (all)	1261		
Sluggishness			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Swelling			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Temperature intolerance			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Temperature regulation disorder			
subjects affected / exposed	7 / 8687 (0.08%)		
occurrences (all)	8		
Tenderness			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Thirst			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Vaccination site erythema			
subjects affected / exposed	51 / 8687 (0.59%)		
occurrences (all)	58		
Vaccination site induration			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Vaccination site inflammation			

subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Vaccination site irritation subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Vaccination site mass subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Vaccination site oedema subjects affected / exposed occurrences (all)	8 / 8687 (0.09%) 8		
Vaccination site pain subjects affected / exposed occurrences (all)	135 / 8687 (1.55%) 156		
Vaccination site paraesthesia subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Vaccination site pruritus subjects affected / exposed occurrences (all)	11 / 8687 (0.13%) 12		
Vaccination site rash subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 2		
Vaccination site swelling subjects affected / exposed occurrences (all)	37 / 8687 (0.43%) 40		
Vaccination site warmth subjects affected / exposed occurrences (all)	7 / 8687 (0.08%) 7		
Vessel puncture site bruise subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Injection site joint swelling subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Immune system disorders			

Allergy to animal subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Allergy to arthropod bite subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Food allergy subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Hypersensitivity subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Multiple allergies subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Reaction to food additive subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Seasonal allergy subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Breast cyst subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Breast enlargement subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Breast pain subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Pelvic pain			

subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Postmenopausal haemorrhage subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Prostatitis subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Vulvar erosion subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Respiratory, thoracic and mediastinal disorders			
Allergic bronchitis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Asthma subjects affected / exposed occurrences (all)	9 / 8687 (0.10%) 10		
Bronchiectasis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Bronchitis chronic subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Bronchospasm subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Catarrh subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Chronic obstructive pulmonary disease			

subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Cough			
subjects affected / exposed	91 / 8687 (1.05%)		
occurrences (all)	96		
Dysphonia			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Dyspnoea			
subjects affected / exposed	9 / 8687 (0.10%)		
occurrences (all)	9		
Dyspnoea exertional			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	11 / 8687 (0.13%)		
occurrences (all)	13		
Laryngeal pain			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Lower respiratory tract congestion			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	18 / 8687 (0.21%)		
occurrences (all)	19		
Nasal disorder			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Nasal obstruction			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Oropharyngeal pain			
subjects affected / exposed	52 / 8687 (0.60%)		
occurrences (all)	57		
Pharyngeal swelling			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Productive cough subjects affected / exposed occurrences (all)	7 / 8687 (0.08%) 7		
Pulmonary congestion subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Respiratory disorder subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Rhinitis allergic subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Rhinorrhoea subjects affected / exposed occurrences (all)	19 / 8687 (0.22%) 20		
Sinus congestion subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Sinus pain subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Sleep apnoea syndrome subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Sneezing subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Sputum discoloured subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Upper respiratory tract inflammation subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Upper-airway cough syndrome			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Depressed mood			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences (all)	6		
Depression			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Generalised anxiety disorder			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	32 / 8687 (0.37%)		
occurrences (all)	34		
Irritability			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	2		
Listless			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Middle insomnia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Restlessness			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Sleep disorder			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences (all)	6		

Investigations			
Blood cholesterol increased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blood iron decreased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blood pressure decreased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blood pressure diastolic increased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blood pressure increased			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Blood triglycerides increased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blood urea decreased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blood uric acid increased			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Body temperature increased			
subjects affected / exposed	76 / 8687 (0.87%)		
occurrences (all)	86		
Cardiac murmur			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Haemoglobin decreased			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Heart rate increased subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Injury, poisoning and procedural complications			
Alcohol poisoning subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 2		
Animal bite subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Arthropod bite subjects affected / exposed occurrences (all)	8 / 8687 (0.09%) 8		
Arthropod sting subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Bone contusion subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Cervical vertebral fracture subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Contusion subjects affected / exposed occurrences (all)	11 / 8687 (0.13%) 11		
Deafness traumatic subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Ear injury subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Epicondylitis			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Face injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Facial bones fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	11 / 8687 (0.13%)		
occurrences (all)	12		
Foot fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Head injury			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Heat stroke			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Joint injury			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Ligament rupture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Ligament sprain			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Limb injury			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Lumbar vertebral fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Muscle rupture			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Muscle strain			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Post procedural complication			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Radius fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Skin injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Skin laceration			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Snake bite			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Soft tissue injury			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	2		
Splinter			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Sternal fracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Subcutaneous haematoma			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Subdural haematoma subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Tendon injury subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Tendon rupture subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 2		
Tooth fracture subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Tooth injury subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Traumatic arthritis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Traumatic haematoma subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Wound subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Wrist fracture subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Arrhythmia subjects affected / exposed occurrences (all)	9 / 8687 (0.10%) 11		

Atrial fibrillation			
subjects affected / exposed	11 / 8687 (0.13%)		
occurrences (all)	11		
Atrioventricular block			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Cardiac failure chronic			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Cardiac failure congestive			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Cardiovascular disorder			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Chronic left ventricular failure			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Dilatation ventricular			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Extrasystoles			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Hypertensive heart disease			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Mitral valve incompetence			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Mitral valve prolapse			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Myocardial ischaemia			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		

Palpitations			
subjects affected / exposed	10 / 8687 (0.12%)		
occurrences (all)	11		
Pericardial effusion			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Supraventricular tachycardia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tachyarrhythmia			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Tachycardia			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Nervous system disorders			
Aphonia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Ataxia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Balance disorder			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Burning sensation			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Carpal tunnel syndrome			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Cerebral ischaemia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Cervical radiculopathy			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Cervicobrachial syndrome subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Cognitive disorder subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Dementia alzheimer's type subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Dizziness subjects affected / exposed occurrences (all)	117 / 8687 (1.35%) 126		
Dysgeusia subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Essential tremor subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Facial paralysis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Hand-arm vibration syndrome subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Head discomfort subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Headache subjects affected / exposed occurrences (all)	678 / 8687 (7.80%) 896		
Hyperaesthesia subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Hypersomnia			

subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
<b>Hypoaesthesia</b>			
subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
<b>Intercostal neuralgia</b>			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
<b>Lethargy</b>			
subjects affected / exposed occurrences (all)	27 / 8687 (0.31%) 31		
<b>Loss of consciousness</b>			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
<b>Memory impairment</b>			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
<b>Mental impairment</b>			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 3		
<b>Migraine</b>			
subjects affected / exposed occurrences (all)	15 / 8687 (0.17%) 18		
<b>Morton's neuralgia</b>			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
<b>Muscle contractions involuntary</b>			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
<b>Myasthenia gravis</b>			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
<b>Neuralgia</b>			
subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
<b>Paraesthesia</b>			

subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Poor quality sleep subjects affected / exposed occurrences (all)	5 / 8687 (0.06%) 6		
Presyncope subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Radiculopathy subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Sciatica subjects affected / exposed occurrences (all)	15 / 8687 (0.17%) 15		
Sensory disturbance subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Sinus headache subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Somnolence subjects affected / exposed occurrences (all)	22 / 8687 (0.25%) 22		
Syncope subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Taste disorder subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Tension headache subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Transient ischaemic attack subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Tremor			

<p>subjects affected / exposed occurrences (all)</p> <p>Trigeminal neuralgia subjects affected / exposed occurrences (all)</p> <p>Vertebral artery occlusion subjects affected / exposed occurrences (all)</p>	<p>13 / 8687 (0.15%) 13</p> <p>2 / 8687 (0.02%) 2</p> <p>1 / 8687 (0.01%) 1</p>		
<p>Blood and lymphatic system disorders</p> <p>Anaemia subjects affected / exposed occurrences (all)</p> <p>Increased tendency to bruise subjects affected / exposed occurrences (all)</p> <p>Lymph node pain subjects affected / exposed occurrences (all)</p> <p>Lymphadenopathy subjects affected / exposed occurrences (all)</p> <p>Pseudolymphoma subjects affected / exposed occurrences (all)</p>	<p>4 / 8687 (0.05%) 4</p> <p>1 / 8687 (0.01%) 1</p> <p>1 / 8687 (0.01%) 1</p> <p>3 / 8687 (0.03%) 4</p> <p>1 / 8687 (0.01%) 1</p>		
<p>Ear and labyrinth disorders</p> <p>Cerumen impaction subjects affected / exposed occurrences (all)</p> <p>Deafness subjects affected / exposed occurrences (all)</p> <p>Ear pain subjects affected / exposed occurrences (all)</p> <p>Ear pruritus</p>	<p>3 / 8687 (0.03%) 3</p> <p>2 / 8687 (0.02%) 2</p> <p>12 / 8687 (0.14%) 12</p>		

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Excessive cerumen production subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Hypoacusis subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Meniere's disease subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Motion sickness subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Tinnitus subjects affected / exposed occurrences (all)	5 / 8687 (0.06%) 6		
Vertigo subjects affected / exposed occurrences (all)	18 / 8687 (0.21%) 20		
Vertigo positional subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Eye disorders			
Accommodation disorder subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Age-related macular degeneration subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Angle closure glaucoma subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Asthenopia subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		

Blepharitis			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Blepharospasm			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Blindness transient			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Cataract			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Conjunctival haemorrhage			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Conjunctivitis allergic			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Dry eye			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Eye haematoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Eye haemorrhage			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Eye inflammation			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Eye irritation			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Eye pain			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences (all)	9		

Eye swelling			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Glaucoma			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Iridocyclitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Lacrimation decreased			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Lacrimation increased			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	3		
Ocular discomfort			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Ocular hyperaemia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Panophthalmitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Photophobia			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Retinal disorder			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Retinal drusen			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Retinal haemorrhage			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		

Retinal vein occlusion subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Swelling of eyelid subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Ulcerative keratitis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Vision blurred subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	10 / 8687 (0.12%) 11		
Abdominal distension subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Abdominal pain subjects affected / exposed occurrences (all)	14 / 8687 (0.16%) 15		
Abdominal pain lower subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Abdominal pain upper subjects affected / exposed occurrences (all)	39 / 8687 (0.45%) 45		
Anal inflammation subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Angular cheilitis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Anorectal discomfort			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Cheilitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Colitis			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Constipation			
subjects affected / exposed	26 / 8687 (0.30%)		
occurrences (all)	26		
Crohn's disease			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Dental caries			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Diarrhoea			
subjects affected / exposed	107 / 8687 (1.23%)		
occurrences (all)	114		
Diverticulum			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Dry mouth			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences (all)	9		
Dyspepsia			
subjects affected / exposed	19 / 8687 (0.22%)		
occurrences (all)	20		
Dysphagia			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Enteritis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Epigastric discomfort			

subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Eructation			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Faeces soft			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Flatulence			
subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Food poisoning			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Gastric disorder			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Gastric ulcer			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Gastritis			
subjects affected / exposed occurrences (all)	8 / 8687 (0.09%) 9		
Gastrointestinal disorder			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Gastritis erosive			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Gastrointestinal motility disorder			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Gastrointestinal pain			
subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 4		
Gingival bleeding			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	12 / 8687 (0.14%)		
occurrences (all)	12		
Gingival ulceration			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Glossodynia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Haematochezia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Haemorrhoids			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Irritable bowel syndrome			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Large intestine polyp			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Lip pain			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Lip swelling			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Lip ulceration			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Mouth swelling			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Mouth ulceration			

subjects affected / exposed	6 / 8687 (0.07%)		
occurrences (all)	6		
Nausea			
subjects affected / exposed	164 / 8687 (1.89%)		
occurrences (all)	184		
Odynophagia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Oesophagitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Oral discomfort			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	2		
Oral mucosal blistering			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Oral pain			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Pancreatitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Paraesthesia oral			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	3		
Peptic ulcer			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Periodontal disease			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Proctitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Rectal haemorrhage			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Rectal tenesmus			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Reflux gastritis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Retching			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Salivary gland calculus			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Stomatitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tongue blistering			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tongue dry			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tongue ulceration			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tooth disorder			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	14 / 8687 (0.16%)		
occurrences (all)	14		
Vomiting			
subjects affected / exposed	37 / 8687 (0.43%)		
occurrences (all)	38		
Hepatobiliary disorders			

Biliary colic			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Cholelithiasis			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Hepatic function abnormal			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Hepatic steatosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Actinic keratosis			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Blister			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences (all)	8		
Cold sweat			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Decubitus ulcer			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Dermal cyst			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Dermatitis			
subjects affected / exposed	16 / 8687 (0.18%)		
occurrences (all)	16		
Dermatitis allergic			

subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Dermatitis atopic			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Dermatitis contact			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Dry skin			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Ecchymosis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Eczema			
subjects affected / exposed	26 / 8687 (0.30%)		
occurrences (all)	27		
Eczema asteatotic			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	29 / 8687 (0.33%)		
occurrences (all)	30		
Generalised erythema			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Haemorrhage subcutaneous			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Hyperhidrosis			
subjects affected / exposed	22 / 8687 (0.25%)		
occurrences (all)	23		
Hyperkeratosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Intertrigo			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Macule			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Night sweats			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Papule			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Pruritus			
subjects affected / exposed	57 / 8687 (0.66%)		
occurrences (all)	62		
Pruritus generalised			
subjects affected / exposed	11 / 8687 (0.13%)		
occurrences (all)	11		
Psoriasis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Purpura			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	49 / 8687 (0.56%)		
occurrences (all)	51		
Rash erythematous			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Rash generalised			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Rash macular			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Rash maculovesicular			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Rash papular subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Rash pruritic subjects affected / exposed occurrences (all)	5 / 8687 (0.06%) 5		
Rosacea subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Seborrhoeic dermatitis subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Sensitive skin subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Skin fissures subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Skin lesion subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Skin odour abnormal subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Skin ulcer subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 3		
Urticaria subjects affected / exposed occurrences (all)	9 / 8687 (0.10%) 11		
Urticaria contact subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Vasculitic ulcer			

subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
<b>Renal and urinary disorders</b>			
Acute kidney injury subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Bladder prolapse subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Calculus urinary subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Chromaturia subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Chronic kidney disease subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Dysuria subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Ketonuria subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Nephroangiosclerosis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Nephrolithiasis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Nocturia subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Pollakiuria subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		

Polyuria			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Renal failure			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Renal impairment			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Renal pain			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Urethral polyp			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Urethral stenosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Endocrine disorders			
Hyperparathyroidism secondary			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Hypothyroidism			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	212 / 8687 (2.44%)		
occurrences (all)	237		
Arthritis			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Arthritis reactive			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Arthropathy			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	100 / 8687 (1.15%)		
occurrences (all)	106		
Bone decalcification			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Bone pain			
subjects affected / exposed	13 / 8687 (0.15%)		
occurrences (all)	14		
Bursitis			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Coccydynia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Costochondritis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Exostosis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Fibromyalgia			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Foot deformity			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Gouty arthritis			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Groin pain			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Growing pains			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Intervertebral disc protrusion			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Intervertebral disc space narrowing			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Joint range of motion decreased			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	3		
Joint stiffness			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Joint swelling			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences (all)	8		
Limb discomfort			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	5		
Muscle contracture			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Muscle fatigue			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Muscle spasms			
subjects affected / exposed	24 / 8687 (0.28%)		
occurrences (all)	30		
Muscle tightness			

subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Muscle twitching subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Muscular weakness subjects affected / exposed occurrences (all)	11 / 8687 (0.13%) 12		
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Musculoskeletal discomfort subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Musculoskeletal pain subjects affected / exposed occurrences (all)	53 / 8687 (0.61%) 55		
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	17 / 8687 (0.20%) 18		
Myalgia subjects affected / exposed occurrences (all)	386 / 8687 (4.44%) 481		
Myalgia intercostal subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Myosclerosis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Myositis subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Neck pain subjects affected / exposed occurrences (all)	42 / 8687 (0.48%) 43		
Nuchal rigidity			

subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Osteitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Osteoarthritis			
subjects affected / exposed	27 / 8687 (0.31%)		
occurrences (all)	30		
Osteopenia			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Osteoporosis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	103 / 8687 (1.19%)		
occurrences (all)	115		
Pain in jaw			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Patellofemoral pain syndrome			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Periarthritis			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Plantar fasciitis			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Polymyalgia rheumatica			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Rheumatoid arthritis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Rotator cuff syndrome			

subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Scoliosis			
subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Senile osteoporosis			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Spinal osteoarthritis			
subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Spinal pain			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Spondyloarthropathy			
subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Synovial cyst			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Temporomandibular joint syndrome			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Tendon pain			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Tendonitis			
subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Tenosynovitis			
subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Torticollis			
subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 3		
Infections and infestations			

Abscess			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Acarodermatitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Acute sinusitis			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Blastocystis infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Borrelia infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Bronchiolitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	40 / 8687 (0.46%)		
occurrences (all)	41		
Cellulitis			
subjects affected / exposed	8 / 8687 (0.09%)		
occurrences (all)	8		
Chronic sinusitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	18 / 8687 (0.21%)		
occurrences (all)	18		
Cystitis			
subjects affected / exposed	17 / 8687 (0.20%)		
occurrences (all)	17		
Dacryocystitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		

Dengue fever			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Dermatophytosis of nail			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Diverticulitis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Ear infection			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences (all)	6		
Erysipelas			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Eye infection			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Folliculitis			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Fungal infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Fungal skin infection			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Furuncle			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Gastric infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	17 / 8687 (0.20%)		
occurrences (all)	17		

Gastroenteritis viral subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Gastrointestinal viral infection subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Genital herpes subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Gingivitis subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Helicobacter infection subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Herpes simplex subjects affected / exposed occurrences (all)	19 / 8687 (0.22%) 22		
Hordeolum subjects affected / exposed occurrences (all)	5 / 8687 (0.06%) 5		
Impetigo subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Influenza subjects affected / exposed occurrences (all)	52 / 8687 (0.60%) 54		
Injection site cellulitis subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Injection site infection subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Labyrinthitis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		

Localised infection			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Lower respiratory tract infection			
subjects affected / exposed	21 / 8687 (0.24%)		
occurrences (all)	21		
Lyme disease			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	228 / 8687 (2.62%)		
occurrences (all)	239		
Onychomycosis			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Oral candidiasis			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Oral fungal infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	31 / 8687 (0.36%)		
occurrences (all)	34		
Oral infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Otitis externa			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Otitis media			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Pathogen resistance			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		

Periodontitis			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Pertussis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	16 / 8687 (0.18%)		
occurrences (all)	16		
Pharyngotonsillitis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences (all)	6		
Pulpitis dental			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Pyelonephritis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		
Respiratory tract infection			
subjects affected / exposed	13 / 8687 (0.15%)		
occurrences (all)	13		
Respiratory tract infection viral			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Rhinitis			
subjects affected / exposed	18 / 8687 (0.21%)		
occurrences (all)	18		
Sinusitis			
subjects affected / exposed	25 / 8687 (0.29%)		
occurrences (all)	26		
Skin candida			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		

Skin infection			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	3		
Subcutaneous abscess			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Syphilis			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Testicular abscess			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tinea infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tinea pedis			
subjects affected / exposed	6 / 8687 (0.07%)		
occurrences (all)	7		
Tongue fungal infection			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tonsillitis			
subjects affected / exposed	5 / 8687 (0.06%)		
occurrences (all)	5		
Tooth abscess			
subjects affected / exposed	1 / 8687 (0.01%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	4 / 8687 (0.05%)		
occurrences (all)	4		
Tracheitis			
subjects affected / exposed	3 / 8687 (0.03%)		
occurrences (all)	4		
Tracheobronchitis			
subjects affected / exposed	2 / 8687 (0.02%)		
occurrences (all)	2		

Upper respiratory tract infection subjects affected / exposed occurrences (all)	80 / 8687 (0.92%) 86		
Urinary tract infection subjects affected / exposed occurrences (all)	63 / 8687 (0.73%) 66		
Vaginal infection subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Vaginitis gardnerella subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Viral infection subjects affected / exposed occurrences (all)	6 / 8687 (0.07%) 6		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Zika virus infection subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	15 / 8687 (0.17%) 15		
Dehydration subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		
Dyslipidaemia subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Gout subjects affected / exposed occurrences (all)	12 / 8687 (0.14%) 12		
Hypercholesterolaemia			

subjects affected / exposed occurrences (all)	8 / 8687 (0.09%) 8		
Hyperglycaemia subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Hyperlipidaemia subjects affected / exposed occurrences (all)	4 / 8687 (0.05%) 4		
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Hyperuricaemia subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 3		
Hypoglycaemia subjects affected / exposed occurrences (all)	3 / 8687 (0.03%) 4		
Hypovitaminosis subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	7 / 8687 (0.08%) 7		
Vitamin b12 deficiency subjects affected / exposed occurrences (all)	1 / 8687 (0.01%) 1		
Vitamin d deficiency subjects affected / exposed occurrences (all)	2 / 8687 (0.02%) 2		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 December 2015	<ul style="list-style-type: none"><li data-bbox="418 360 1422 477">• Occurrence of suspected Herpes Zoster (HZ) episodes during the entire study period were evaluated as secondary objective. Therefore, wording related to collection, reporting and recording of HZ was added where applicable throughout the protocol.</li><li data-bbox="418 477 1422 533">• Other minor changes have been made to correct typos and improve clarity and alignment within the document.</li></ul>

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported