Clinical trial results:
A Comparison of LY2605541 Versus Insulin Glargine as Basal Insulin Treatment in Combination With Oral Anti-Hyperglycemia Medications in Insulin-Naive Patients With Type 2 Diabetes Mellitus: A Double-Blind, Randomized Study .

Summary

EudraCT number	2011-000842-39
Trial protocol	HU SK GB CZ DE LT ES GR FI IT
Global end of trial date	16 January 2014

Results information

Result version number	v1 (current)
This version publication date	02 April 2018
First version publication date	02 April 2018

Trial information

Trial identification

Sponsor protocol code	I2R-MC-BIAJ

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01435616
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12141

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

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	16 January 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to demonstrate that LY2605541 is noninferior to insulin glargine for the change in HbA1c from baseline to 52 weeks of treatment in insulin naive patients with Type 2 Diabetes Mellitus (T2DM).

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 559
Country: Number of subjects enrolled	Turkey: 11
Country: Number of subjects enrolled	Israel: 24
Country: Number of subjects enrolled	Russian Federation: 50
Country: Number of subjects enrolled	Mexico: 40
Country: Number of subjects enrolled	Puerto Rico: 58
Country: Number of subjects enrolled	Canada: 27
Country: Number of subjects enrolled	Argentina: 101
Country: Number of subjects enrolled	Brazil: 30
Country: Number of subjects enrolled	Romania: 62
Country: Number of subjects enrolled	Australia: 45
Country: Number of subjects enrolled	South Africa: 15
Country: Number of subjects enrolled	New Zealand: 19
Country: Number of subjects enrolled	Poland: 99
Country: Number of subjects enrolled	Slovakia: 22
Country: Number of subjects enrolled	Spain: 53
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	Czech Republic: 13
Country: Number of subjects enrolled	Finland: 13

Country: Number of subjects enrolled	Germany: 99
Country: Number of subjects enrolled	Greece: 30
Country: Number of subjects enrolled	Hungary: 102
Country: Number of subjects enrolled	Italy: 37
Country: Number of subjects enrolled	Lithuania: 12
Worldwide total number of subjects	1538
EEA total number of subjects	559

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1066
From 65 to 84 years	469
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

No text entered

Pre-assignment

Screening details:

No text entered

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	LY2605541

Arm description:

LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks

Arm type	Experimental
Investigational medicinal product name	LY2605541
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks.

Arm title	Glargine

Arm description:

Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.

Arm type	Active comparator
Investigational medicinal product name	Glargine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.

Number of subjects in period 1	LY2605541	Glargine
Started	1003	535
Received at Least 1 Dose of Study Drug	1003	535
Completed	832	455
Not completed	171	80
Adverse event, serious fatal	7	2
Consent withdrawn by subject	66	24
Physician decision	20	7
Adverse event, non-fatal	39	21
Sponsor Decision	1	-
Lost to follow-up	22	13
Protocol deviation	16	13

Baseline characteristics

Reporting groups	
Reporting group title	LY2605541
Reporting group description:	
LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks	
Reporting group title	Glargine
Reporting group description:	
Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.	

Reporting group values	LY2605541	Glargine	Total
Number of subjects	1003	535	1538
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	58.80	59.35	
standard deviation	± 9.86	± 9.80	-
Gender categorical			
Units: Subjects			
Female	453	227	680
Male	550	308	858
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	201	96	297
Not Hispanic or Latino	648	355	1003
Unknown or Not Reported	154	84	238
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	24	15	39
Asian	25	12	37
Native Hawaiian or Other Pacific Islander	3	2	5
Black or African American	68	34	102
White	875	469	1344
More than one race	8	3	11
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	LY2605541
Reporting group description:	
LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks	
Reporting group title	Glargine
Reporting group description:	
Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.	

Primary: Change From Baseline to 52 Week Endpoint in Hemoglobin A1c (HbA1c)

End point title	Change From Baseline to 52 Week Endpoint in Hemoglobin A1c (HbA1c)
End point description:	
HbA1C is a test that measures a person's average blood glucose level over the past 2 to 3 months. Least Squares (LS) means were calculated using a mixed model repeated measures (MMRM) with baseline HbA1c measurement, stratification factors (country, low density lipoprotein-cholesterol [LDL-C, < 100 milligrams per deciliter {mg/dL} and ≥ 100 mg/dL] and sulfonylurea [SU]/meglitinide use), visit, treatment, and visit-by-treatment interaction as fixed effects.	
End point type	Primary
End point timeframe:	
Baseline, 52 weeks	
Analysis Population Description: All participants who were randomized, had at least 1 dose of study medication, and at least 1 post-baseline HbA1c measurement.	

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of HbA1c				
least squares mean (standard error)	-1.55 (± 0.03)	-1.25 (± 0.04)		

Statistical analyses

Statistical analysis title	HbA1c Statistical Analysis
Comparison groups	LY2605541 v Glargine
Number of subjects included in analysis	1512
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.001
Method	Mixed Model Repeated Measures (MMRM)
Parameter estimate	LS Mean Difference
Point estimate	-0.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	-0.19

Secondary: Rate of Total and Nocturnal Hypoglycemia Events

End point title	Rate of Total and Nocturnal Hypoglycemia Events

End point description:

Hypoglycemia is a condition that occurs when a person's blood glucose level is lower than the normal range (less than or equal to 70 milligrams per deciliter [mg/dL] or less than 3.9 millimoles per liter [mmol/L]). Total hypoglycemia refers to an event that meets the criteria for documented symptomatic hypoglycemia, asymptomatic hypoglycemia, probable symptomatic hypoglycemia, unspecified hypoglycemia, or severe hypoglycemia. Nocturnal hypoglycemia refers to any total hypoglycemic event that occurs between bedtime and waking. Group mean (listed as LS means below) rates of total and nocturnal hypoglycemia were calculated using a negative binomial regression model (number of episodes = treatment + SU/meglitinide use + baseline hypoglycemia event rate, with log [exposure per 30 days] as the offset variable in the model).

End point type	Secondary

End point timeframe:

Baseline to 52 weeks

Analysis Population Description: All participants who were randomized, who received at least 1 dose of study drug, and had evaluable total and/or nocturnal event data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1001	535		
Units: episodes/participant/30 days				
least squares mean (standard error)				
Rate of total hypoglycemia events	1.16 (± 0.06)	1.21 (± 0.07)		
Rate of nocturnal hypoglycemia events	0.30 (± 0.05)	0.40 (± 0.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Hemoglobin A1c Equal or Less Than 6.5% and Less Than 7.0 %

End point title	Percentage of Participants With Hemoglobin A1c Equal or Less Than 6.5% and Less Than 7.0 %

End point description:

The percentage of participants was calculated by dividing the number of participants reaching target HbA1c by the total number of participants analyzed, multiplied by 100.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline HbA1c measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of participants				
number (not applicable)				
HbA1c ≤ 6.5%	36.1	23.9		
HbA1c < 7.0%	57.6	42.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Fasting Serum Glucose (By Laboratory Measurement)

End point title	Fasting Serum Glucose (By Laboratory Measurement)

End point description:

LS means were calculated using a MMRM with baseline fasting serum glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable fasting serum glucose data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	986	521		
Units: mg/dL				
least squares mean (standard error)	114.93 (± 1.24)	120.13 (± 1.70)		

Statistical analyses

No statistical analyses for this end point

Secondary: Fasting Blood Glucose (By Participant Self-monitored Blood Glucose Readings)

End point title	Fasting Blood Glucose (By Participant Self-monitored Blood

	Glucose Readings)

End point description:

LS means were calculated using a MMRM with baseline fasting blood glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable fasting blood glucose data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	994	528		
Units: mg/dL				
least squares mean (standard error)	112.57 (± 0.82)	112.00 (± 1.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: 6 Point Self-monitored Blood Glucose (SMBG)

End point title	6 Point Self-monitored Blood Glucose (SMBG)

End point description:

Six-point SMBG profiles were obtained at pre-morning meal (fasting), pre-midday meal (lunch), pre-evening meal (dinner), bedtime, approximately 0300 hours, and pre-morning meal (fasting) the next day. Six-point SMBG profiles were obtained over 2 nonconsecutive days within the week prior to the next office visit. LS means were calculated using a MMRM with baseline blood glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable SMBG data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	943	499		
Units: mg/dL				
least squares mean (standard error)				
Pre-morning meal (n=943, n=499)	112.81 (± 0.96)	112.26 (± 1.31)		

Pre-midday meal (n=925, n=494)	127.65 (± 1.36)	134.52 (± 1.86)		
Pre-evening meal (n=928, n=494)	133.94 (± 1.40)	142.58 (± 1.91)		
Bedtime (n=911, n=486)	151.37 (± 1.54)	155.19 (± 2.10)		
0300 hours (n=909, n=466)	120.35 (± 1.21)	118.37 (± 1.67)		
Pre-morning meal (next day)(n=939, n=494)	111.11 (± 0.89)	109.19 (± 1.23)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 52 Weeks in Body Weight

End point title	Change From Baseline to 52 Weeks in Body Weight

End point description:

LS means were calculated using a MMRM with baseline body weight measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

Analysis Population Description: All participants who were randomized, who received at least 1 dose of study drug, and had evaluable body weight data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	985	522		
Units: kilograms (kg)				
least squares mean (standard error)	2.06 (± 0.15)	2.57 (± 0.21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Hemoglobin A1c

End point title	Hemoglobin A1c

End point description:

HbA1c is a test that measures a person's average blood glucose level over the past 2 to 3 months. LS means were calculated using a MMRM with baseline HbA1C measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline HbA1c measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of HbA1c				
least squares mean (standard error)	6.91 (± 0.03)	7.21 (± 0.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Insulin Dose Per Body Weight

End point title	Insulin Dose Per Body Weight

End point description:

LS means were calculated using a MMRM with baseline insulin dose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable insulin dose data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1001	532		
Units: units of insulin/kg body weight				
least squares mean (standard error)	0.45 (± 0.01)	0.42 (± 0.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Insulin Dose Adjustments to Steady-State

End point title	Number of Insulin Dose Adjustments to Steady-State

End point description:

Insulin doses were adjusted according to an algorithm (adapted from Riddle et al. 2003) during the first

26 weeks of the study and thereafter according to investigator judgment. Steady-state was defined as the first local maximum dose (maximum of moving 4-week interval) of LY2605541 or glargine within the window of +/- 2 weeks. The number of dose adjustments to steady-state was the total number of dose changes until steady-state was reached. LS means were calculated using a MMRM with baseline insulin dose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable post-baseline insulin data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1002	532		
Units: number of insulin dose adjustments				
least squares mean (standard error)	5.83 (± 0.12)	5.25 (± 0.16)		

Statistical analyses

No statistical analyses for this end point

Secondary: European Quality of Life-5 Dimension (EQ-5D)

End point title	European Quality of Life-5 Dimension (EQ-5D)

End point description:

The EQ-5D is a generic, multidimensional, health-related, quality-of-life instrument. The profile allows participants to rate their health state in 5 health domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) using a 3-level scale of 1 to 3 (no problem, some problems, and extreme problems). These combinations of attributes are converted into a weighted health-state Index Score according to the United States population-based algorithm. Scores range from -0.11 to 1.0, where a score of 1.0 indicates perfect health. LS means were calculated using a MMRM with baseline stratification factors (country, HbA1c, and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable EQ-5D data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	892	474		
Units: units on a scale				
least squares mean (standard error)	0.88 (± 0.00)	0.88 (± 0.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Insulin Treatment Satisfaction Questionnaire

End point title	Insulin Treatment Satisfaction Questionnaire

End point description:

The Insulin Treatment Satisfaction Questionnaire (ITSQ) is a validated instrument containing 22 items that assess treatment satisfaction for participants with diabetes who are receiving insulin. The questionnaire measures satisfaction from the following 5 domains: inconvenience of regimen, lifestyle flexibility, glycemic control, hypoglycemic control, and insulin delivery device. Data presented are the transformed total score on a scale of 0 to 100, where higher scores indicate better treatment satisfaction. LS means were calculated using a MMRM with stratification factors (country, HbA1c, and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Up to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable ITSQ data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	966	515		
Units: Insulin Treatment Satisfaction Questionn				
least squares mean (standard error)	84.73 (± 0.44)	85.04 (± 0.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adult Low Blood Sugar Survey

End point title	Adult Low Blood Sugar Survey

End point description:

The adult Low Blood Sugar Survey (LBSS) is a validated, participant-reported 33-item questionnaire with items rated on a 5-point Likert scale, where 0 = never and 4 = always. The LBSS measures behaviors to avoid hypoglycemia and its negative consequences (15 items) and worries about hypoglycemia and its negative consequences (18 items). Total score is the sum of all items (range of 0 to 132). Higher total scores reflect greater fear of hypoglycemia. LS means were calculated using an analysis of covariance model (ANCOVA) with baseline LBSS score, stratification factors (country, HbA1c, and SU/meglitinide use), and treatment as fixed effects.

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable LBSS data. Missing endpoints were imputed with the last observation carried

forward (LOCF) method, using only post-baseline data.

End point type	Secondary

End point timeframe:

Up to 52 weeks

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	899	478		
Units: Adult Low Blood Sugar Survey				
least squares mean (standard error)	15.09 (± 0.49)	14.59 (± 0.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 52 Weeks in Triglycerides, Low Density Lipoprotein Cholesterol (LDL-C), and High Density Lipoprotein Cholesterol (HDL-C)

End point title	Change From Baseline to 52 Weeks in Triglycerides, Low Density Lipoprotein Cholesterol (LDL-C), and High Density Lipoprotein Cholesterol (HDL-C)

End point description:

LS means were calculated using a MMRM with baseline lipid measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline lipid measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	992	528		
Units: milligrams per deciliter (mg/dL)				
least squares mean (standard error)				
Triglycerides (n=992, n=528)	10.60 (± 2.46)	-7.33 (± 3.38)		
LDL-C (n=992, n=527)	1.44 (± 0.83)	1.76 (± 1.14)		
HDL-C (n=992, n=528)	-1.91 (± 0.21)	-1.82 (± 0.29)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Equal or Above 2-, and 3-fold Upper Limits of Normal (ULN) for Total Bilirubin

End point title	Percentage of Participants With Equal or Above 2-, and 3-fold Upper Limits of Normal (ULN) for Total Bilirubin

End point description:

End point type	Secondary

End point timeframe:

Up to 52 weeks

Analysis Population Description: All participants who were randomized, had at least 1 dose of study drug, and had at least 1 post-baseline total bilirubin measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	994	529		
Units: Percentage of Participants With Equal or				
number (not applicable)				
≥2-fold ULN	0.2	0.0		
≥3-fold ULN	0.1	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Treatment-Emergent Anti-LY2065541 Antibody Response (TEAR)

End point title	Overall Treatment-Emergent Anti-LY2065541 Antibody Response (TEAR)

End point description:

The percentage of participants with a TEAR is summarized. TEAR is defined as a change in the anti-LY2605541 antibody level from undetectable at baseline to detectable at baseline, or, for those participants with detectable antibodies at baseline, change to a value with at least a 130% relative increase from baseline. Overall TEAR is defined as one or more TEAR during the specified period.

End point type	Secondary

End point timeframe:

Baseline to 78 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable TEAR data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	988	521		
Units: percentage of participants				
number (not applicable)	43.0	37.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-participant Variability of the Fasting Blood Glucose (FBG)

End point title	Intra-participant Variability of the Fasting Blood Glucose (FBG)

End point description:

Intra-participant variability of FBG, which was measured by SMBG, was assessed by the standard deviation of the FBG measurement at the Week 52 visit. LS means were calculated using a MMRM with baseline fasting blood glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable post-baseline FBG data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	991	522		
Units: mg/dL				
least squares mean (standard error)	15.56 (± 0.38)	17.08 (± 0.52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Total and Nocturnal Hypoglycemic Events

End point title	Percentage of Participants With Total and Nocturnal Hypoglycemic Events

End point description:

A hypoglycemic event is defined by a blood glucose value ≤70 mg/dL (3.9mmol/L). Total hypoglycemic events include documented symptomatic hypoglycemia, asymptomatic hypoglycemia, probable symptomatic hypoglycemia, unspecified hypoglycemia, or severe hypoglycemia. Nocturnal hypoglycemic events refer to any total hypoglycemic event that occurs between bedtime and waking. The percentage of participants was calculated by dividing the number of participants with hypoglycemic or nocturnal hypoglycemic events by the total number of participants analyzed, multiplied by 100.

End point type	Secondary

End point timeframe:

Baseline to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable hypoglycemia event data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1001	535		
Units: percentage of participants				
number (not applicable)				
Total hypoglycemic events	77.0	79.8		
Nocturnal hypoglycemic events	48.9	59.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HbA1C Equal or Less Than 6.5% and Less Than 7.0 % and Without Nocturnal Hypoglycemia

End point title	Percentage of Participants With HbA1C Equal or Less Than 6.5% and Less Than 7.0 % and Without Nocturnal Hypoglycemia

End point description:

The percentage of participants with HbA1C ≤ 6.5% or < 7.0% without nocturnal hypoglycemia is presented. Percentage was calculated by dividing the number of participants with the indicated HbA1c values over the total number of participants and multiplying by 100.

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline HbA1c measurement. Missing endpoints were imputed with the LOCF method, using only post-baseline data.

End point type	Secondary

End point timeframe:

Up to 52 weeks

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of participants				
number (not applicable)				
HbA1c ≤ 6.5%	17.5	8.6		
HbA1c < 7.0%	26.2	15.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Equal or Above 2- and 3-fold ULN for Alanine Transaminase/Serum Glutamic Pyruvic Transaminase (ALT/SGPT) and Aspartate Transaminase/Serum Glutamic Oxaloacetic Transaminase (AST/SGOT)

End point title	Percentage of Participants With Equal or Above 2- and 3-fold ULN for Alanine Transaminase/Serum Glutamic Pyruvic Transaminase (ALT/SGPT) and Aspartate Transaminase/Serum Glutamic Oxaloacetic Transaminase (AST/SGOT)

End point description:

The percentage of participants was calculated by dividing the number of participants equal or above 2- or 3-fold ULN for ALT/SGPT or AST/SGOT by the total number of participants analyzed, multiplied by 100.

End point type	Secondary

End point timeframe:

Up to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable post-baseline liver enzyme data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	990	524		
Units: percentage of participants				
number (not applicable)				
≥2-fold ULN for ALT	6.5	4.0		
≥3-fold ULN for ALT	1.9	0.6		
≥2-fold ULN for AST	3.6	1.5		
≥3-fold ULN for AST	1.0	0.4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Analysis Period 2 (AP2)	
Adverse event reporting additional description:	
I2R-MC-BIAJ	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups	
Reporting group title	Glargine
Reporting group description: -	
Reporting group title	LY2605541
Reporting group description: -	

Serious adverse events	Glargine	LY2605541	
Total subjects affected by serious adverse events			
subjects affected / exposed	73 / 535 (13.64%)	105 / 1003 (10.47%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
adenocarcinoma of colon			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
benign gastric neoplasm			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder transitional cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
endometrial adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lentigo maligna			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

lung adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung neoplasm malignant			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant melanoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to salivary gland			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-small cell lung cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal cancer metastatic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
pancreatic carcinoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer metastatic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer stage iii			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal adenoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

squamous cell carcinoma of the tongue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transitional cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
aortic stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertension			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoperfusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
iliac artery occlusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
shock			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Surgical and medical procedures			
coronary artery bypass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
glossectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostatectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
radical neck dissection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
death			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
device occlusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
sarcoidosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic floor muscle weakness			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pharyngeal cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleuritic pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
weight increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
clavicle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniscus injury			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rib fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
scapula fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thoracic vertebral fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina pectoris			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina unstable			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic valve stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial flutter			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

atrioventricular block			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block complete			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block second degree			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bradycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac arrest			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
cardiac failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac failure congestive			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac tamponade			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertensive heart disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
myocardial ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

right ventricular failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sinus tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
supraventricular tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricular arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
wolff-parkinson-white syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
autonomic neuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebral ischaemia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervicobrachial syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
complex partial seizures			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic neuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhage intracranial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
hemiparesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

ischaemic cerebral infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic stroke			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
lacunar infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischaemic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vestibular ataxia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitreous haemorrhage			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ascites			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric fistula			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroduodenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis eosinophilic			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine perforation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophagitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
cholangitis acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic cirrhosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hydrocholecystis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
skin ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urticaria chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vasculitic rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
renal failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar spinal stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchopneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis infective			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
escherichia bacteraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder empyema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
liver abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
localised infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
necrotising fasciitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
osteomyelitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
sepsis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	7 / 1003 (0.70%)	
occurrences causally related to treatment / all	3 / 4	6 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypokalaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypophagia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Glargine	LY2605541	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	390 / 535 (72.90%)	733 / 1003 (73.08%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acrochordon			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
adenoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
adrenal adenoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
benign breast neoplasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
benign neoplasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
melanocytic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
neoplasm prostate			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
neoplasm skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
prostate cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
seborrhoeic keratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
skin papilloma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
squamous cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
thyroid neoplasm			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tracheal neoplasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
tumour pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
angiopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
aortic arteriosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
aortic stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
arteriosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
blood pressure inadequately controlled			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
diabetic microangiopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
essential hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	2	
flushing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
hot flush			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	12 / 535 (2.24%)	41 / 1003 (4.09%)	
occurrences (all)	12	43	
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)	
occurrences (all)	4	2	

intermittent claudication			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
intra-abdominal haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
lymphoedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
orthostatic hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
peripheral vascular disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
thrombophlebitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
varicose vein			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
venous insufficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
abdominoplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
angioplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
aortic valve replacement			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
apicectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
atherectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blepharoplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
bone lesion excision			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cardiac pacemaker insertion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
carpal tunnel decompression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
cataract operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)	
occurrences (all)	6	4	
cholecystectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)	
occurrences (all)	4	3	
colectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
coronary angioplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
coronary arterial stent insertion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	4	1	
coronary artery bypass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	

cyst removal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
dental care			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
dental disorder prophylaxis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
dental implantation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
dental operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
endodontic procedure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
explorative laparotomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
eye laser surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
finger repair operation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
gastric operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gastric polypectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
haemorrhoid operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hip arthroplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hysterectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
knee arthroplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
laryngeal operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
limb operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	

lithotripsy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
mammoplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
micrographic skin surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
mitral valve replacement			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
mole excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
nail operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
oral surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
percutaneous coronary intervention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
perineoplasty			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
peripheral nerve decompression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pneumonectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
salpingo-oophorectomy bilateral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
sclerotherapy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
skin graft			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
skin neoplasm excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
spermatocele excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
stent placement			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

stent removal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tendon operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
tendon sheath incision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
toe operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tooth extraction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	11 / 1003 (1.10%)	
occurrences (all)	4	12	
tooth repair			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	3	
ureteral stent insertion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
varicose vein operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vitrectomy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	2	
General disorders and administration site conditions			
application site pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 535 (1.31%)	8 / 1003 (0.80%)	
occurrences (all)	8	9	
axillary pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
chest discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	9 / 1003 (0.90%)	
occurrences (all)	1	10	
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	1	6	
chronic fatigue syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cyst			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	4	
drug intolerance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
early satiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
fat tissue increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
fatigue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	14 / 535 (2.62%)	35 / 1003 (3.49%)	
occurrences (all)	15	38	
feeling abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
feeling jittery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
feeling of body temperature change			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

hunger			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
hyperpyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
impaired healing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
influenza like illness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	9 / 1003 (0.90%)	
occurrences (all)	1	9	
infusion site bruising			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
injection site hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	5	
injection site induration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
injection site inflammation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
injection site oedema				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)		
occurrences (all)	0	3		
injection site pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)		
occurrences (all)	2	1		
injection site pruritus				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	1	0		
injection site rash				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
injection site reaction				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
injection site swelling				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)		
occurrences (all)	0	3		
irritability				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
local swelling				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		

malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	4 / 1003 (0.40%)	
occurrences (all)	5	6	
nodule			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	8 / 1003 (0.80%)	
occurrences (all)	3	8	
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	16 / 535 (2.99%)	29 / 1003 (2.89%)	
occurrences (all)	18	34	
pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	12 / 1003 (1.20%)	
occurrences (all)	3	14	
puncture site haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	17 / 1003 (1.69%)	
occurrences (all)	5	18	
spinal pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	4	
therapeutic response unexpected			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
thirst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vessel puncture site bruise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
allergy to arthropod sting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
contrast media allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
food allergy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
reaction to food additive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
seasonal allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 535 (1.31%)	7 / 1003 (0.70%)	
occurrences (all)	7	9	
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	4 / 1003 (0.40%)	
occurrences (all)	3	4	
breast mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
dysmenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	6	
endometrial hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
epididymal cyst			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
epididymitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
erectile dysfunction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)	
occurrences (all)	0	6	
menstruation irregular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
orchitis noninfective			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
pelvic pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
penis disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	

premenstrual syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
prostatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)	
occurrences (all)	5	2	
prostatomegaly			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
scrotal mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
testicular pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	5	
vaginal discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
vulvovaginal pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
allergic sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
apnoeic attack			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)	
occurrences (all)	3	11	
atelectasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	1	4	
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	18 / 535 (3.36%)	44 / 1003 (4.39%)	
occurrences (all)	22	52	
dysphonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
dyspnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	15 / 1003 (1.50%)	
occurrences (all)	2	16	
dyspnoea exertional			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	
emphysema			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
epistaxis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)		
occurrences (all)	4	3		
lung disorder				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
nasal congestion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 535 (0.56%)	8 / 1003 (0.80%)		
occurrences (all)	4	8		
nasal inflammation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
nasal septum deviation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
nasal septum perforation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
oropharyngeal pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	19 / 535 (3.55%)	34 / 1003 (3.39%)		
occurrences (all)	21	40		
orthopnoea				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		

paranasal sinus hypersecretion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
pleural effusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
pleurisy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pneumonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
productive cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	7 / 1003 (0.70%)	
occurrences (all)	0	8	
pulmonary congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pulmonary fibrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pulmonary hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
respiratory disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	6 / 535 (1.12%)	2 / 1003 (0.20%)	
occurrences (all)	6	2	
respiratory distress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
respiratory tract congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	7 / 1003 (0.70%)	
occurrences (all)	1	7	
rhinitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)	
occurrences (all)	3	6	
rhinitis seasonal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
rhinorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
sinus congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)	
occurrences (all)	5	6	
sleep apnoea syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	3 / 1003 (0.30%)	
occurrences (all)	6	3	
sneezing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

throat irritation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
tonsillar inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
upper respiratory tract congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
upper-airway cough syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
wheezing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	4	
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
adjustment disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
affect lability			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
agitation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 535 (1.31%)	11 / 1003 (1.10%)	
occurrences (all)	8	11	
confusional state			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
daydreaming			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	10 / 1003 (1.00%)	
occurrences (all)	6	10	
disorientation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
drug abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	

fear of eating			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	11 / 535 (2.06%)	15 / 1003 (1.50%)	
occurrences (all)	11	16	
libido decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
mental disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
mental disorder due to a general medical condition			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
nervousness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
nightmare			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
obsessive-compulsive disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
panic attack			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
personality disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
phonophobia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
restlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
sleep disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	4	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	24 / 1003 (2.39%)	
occurrences (all)	3	25	
amino acid level increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
angiogram			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
antinuclear antibody positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
arteriogram coronary			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	15 / 1003 (1.50%)	
occurrences (all)	2	15	
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blood bicarbonate increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blood bilirubin increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blood calcium increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blood creatine increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	12 / 535 (2.24%)	9 / 1003 (0.90%)	
occurrences (all)	12	9	
blood creatinine increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blood iron decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blood lactate dehydrogenase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
blood magnesium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
blood potassium increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
blood pressure increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	3	3	
blood testosterone decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	1 / 1003 (0.10%)	
occurrences (all)	4	1	
blood triglycerides increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	8 / 1003 (0.80%)	
occurrences (all)	0	8	
blood urea increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
blood uric acid increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
blood urine present			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
bronchoscopy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
catheterisation cardiac			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
colonoscopy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	

electrocardiogram p wave abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
electrocardiogram st-t segment abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
electrocardiogram t wave inversion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
electrocardiogram abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
electroencephalogram abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
eosinophil count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gastric ph decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
haematocrit increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
haemoglobin increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
heart rate irregular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
helicobacter test positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
hepatic enzyme abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	
hepatitis b antibody positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
human chorionic gonadotropin abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
human chorionic gonadotropin increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
left ventricular end-diastolic pressure increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
mean cell haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
mean cell volume decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
oesophagogastroduodenoscopy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
platelet count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
prostatic specific antigen increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	3	

protein urine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
protein urine present			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
qrs axis abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
serum ferritin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vitamin d decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
vitamin d increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
waist circumference increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
weight decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
weight increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	18 / 535 (3.36%)	26 / 1003 (2.59%)	
occurrences (all)	18	28	
white blood cell count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
white blood cells urine positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
Injury, poisoning and procedural complications			
anaemia postoperative			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
animal bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
ankle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
arthropod bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	11 / 1003 (1.10%)	
occurrences (all)	7	11	
arthropod sting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
asbestosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
avulsion fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
back injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
bone contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)	
occurrences (all)	3	0	
burns first degree			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
chest crushing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
chest injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	17 / 1003 (1.69%)	
occurrences (all)	9	20	
epicondylitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	

excoriation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	1	8	
exposure to toxic agent			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
facial bones fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)	
occurrences (all)	3	12	
fibula fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	5 / 1003 (0.50%)	
occurrences (all)	2	6	
foreign body			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
foreign body in eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
hand fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	3	
head injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
heat exhaustion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
joint dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)	
occurrences (all)	4	4	
joint injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 535 (1.31%)	2 / 1003 (0.20%)	
occurrences (all)	7	2	
laceration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)	
occurrences (all)	3	9	
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	9 / 535 (1.68%)	6 / 1003 (0.60%)	
occurrences (all)	9	6	
limb injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	2	5	
liver contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	

meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
muscle contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
muscle rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	10 / 1003 (1.00%)	
occurrences (all)	2	10	
nail avulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
nail injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
patella fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pelvic fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
periorbital haematoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
post procedural complication			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
postoperative respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
rib fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
scratch			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
skeletal injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	

soft tissue injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
spinal compression fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
spinal fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
stab wound			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
thermal burn			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
traumatic fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
upper limb fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
vaccination complication			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
wound			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	3 / 1003 (0.30%)	
occurrences (all)	3	3	
Congenital, familial and genetic disorders			
atrial septal defect			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
corneal dystrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
kidney duplex			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
phimosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
type v hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
aortic valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
arrhythmia supraventricular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	3 / 1003 (0.30%)	
occurrences (all)	3	4	
atrioventricular block first degree			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
bradycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
bundle branch block left			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
bundle branch block right			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)	
occurrences (all)	3	0	
cardiac aneurysm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

cardiac arrest			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cardiac failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	3	
cardiac failure congestive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	0 / 1003 (0.00%)	
occurrences (all)	5	0	
cardiomegaly			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
conduction disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
coronary artery disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)	
occurrences (all)	4	3	
coronary ostial stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
diastolic dysfunction			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
extrasystoles			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
ischaemic cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
left ventricular failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
left ventricular hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
mitral valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
myocardial ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
palpitations			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	7 / 1003 (0.70%)	
occurrences (all)	7	8	

pericardial effusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
prinzmetal angina			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pulmonary valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
silent myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
sinus bradycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
sinus tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
supraventricular extrasystoles			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
tachyarrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
tachycardia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
tricuspid valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
ventricular arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
ventricular extrasystoles			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
ventricular hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
ventricular tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
altered state of consciousness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
amnesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	2	
balance disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	1	4	
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)	
occurrences (all)	3	7	
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
cervical root pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cervicobrachial syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
diabetic neuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	9 / 1003 (0.90%)	
occurrences (all)	6	9	
disturbance in attention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	

dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	17 / 535 (3.18%)	32 / 1003 (3.19%)	
occurrences (all)	29	36	
dizziness postural			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)	
occurrences (all)	3	0	
dysgeusia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	37 / 535 (6.92%)	85 / 1003 (8.47%)	
occurrences (all)	72	134	
hemiparesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	14 / 1003 (1.40%)	
occurrences (all)	2	15	
lacunar infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
lethargy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
memory impairment			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
meralgia paraesthetica			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)	
occurrences (all)	4	15	
nerve compression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	
neuralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
neuropathy peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	4 / 1003 (0.40%)	
occurrences (all)	6	6	
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 535 (1.50%)	12 / 1003 (1.20%)	
occurrences (all)	10	13	
parkinsonism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
partial seizures			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	

post-traumatic headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
radiculitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
restless legs syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
sciatica			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	9 / 535 (1.68%)	6 / 1003 (0.60%)	
occurrences (all)	9	7	
sinus headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
somnolence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
spinal cord disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences (all)	0	5	
transient ischaemic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tremor			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
viith nerve paralysis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	1	5	
white matter lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	14 / 1003 (1.40%)	
occurrences (all)	5	17	
anaemia macrocytic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
coagulopathy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
eosinophilia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
hypersplenism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
lymphadenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
lymphadenopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
lymphocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pernicious anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

splenomegaly			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
Ear and labyrinth disorders			
cerumen impaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
deafness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
deafness bilateral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
ear discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
ear pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 535 (1.50%)	7 / 1003 (0.70%)	
occurrences (all)	10	8	
eustachian tube disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
hypoacusis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
otosclerosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tinnitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tympanic membrane perforation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	12 / 1003 (1.20%)	
occurrences (all)	8	13	
vertigo positional			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vestibular disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Eye disorders			
arcus lipoides			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
asthenopia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
blepharitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blepharospasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
blindness unilateral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	10 / 1003 (1.00%)	
occurrences (all)	1	11	
chalazion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
conjunctivitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
conjunctivitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
dacryostenosis acquired			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
diabetic retinopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	6 / 1003 (0.60%)	
occurrences (all)	1	6	

diplopia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
dry eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
eye allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
eye discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
eye haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
eye pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
eye pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
eye swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
glaucoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
iris neovascularisation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
iritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
keratitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
macular oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	3	
maculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
ocular hyperaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
ocular hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
open angle glaucoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

optic ischaemic neuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
photophobia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
retinal exudates			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
retinopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
sudden visual loss			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	3	
vision blurred			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	8 / 1003 (0.80%)	
occurrences (all)	1	9	
visual acuity reduced			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
visual impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
vitreous floaters			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
vitreous haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	9 / 1003 (0.90%)	
occurrences (all)	0	9	
abdominal distension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	8 / 1003 (0.80%)	
occurrences (all)	2	8	
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 535 (1.87%)	13 / 1003 (1.30%)	
occurrences (all)	12	14	
abdominal pain lower			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	19 / 1003 (1.89%)	
occurrences (all)	6	24	
abnormal faeces			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
anal fistula			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
aphthous stomatitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	2	0		
ascites				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	1	0		
barrett's oesophagus				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	1	0		
change of bowel habit				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	2	1		
chapped lips				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
colitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)		
occurrences (all)	2	3		
colitis psychogenic				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)		
occurrences (all)	1	2		
constipation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	7 / 535 (1.31%)	6 / 1003 (0.60%)		
occurrences (all)	7	6		

dental caries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	38 / 535 (7.10%)	57 / 1003 (5.68%)	
occurrences (all)	52	81	
diverticulum			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
dry mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	1	4	
duodenal ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
duodenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	13 / 1003 (1.30%)	
occurrences (all)	7	15	
dysphagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
epigastric discomfort			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
eructation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
faecaloma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
flatulence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)	
occurrences (all)	3	6	
food poisoning			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)	
occurrences (all)	5	6	
gastric mucosa erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gastric polyps			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gastric ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
gastritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)	
occurrences (all)	3	9	

gastritis atrophic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
gastritis erosive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
gastrointestinal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	8 / 1003 (0.80%)	
occurrences (all)	4	8	
gingival disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gingival inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gingival pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
haematochezia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
haemorrhoids			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)		
occurrences (all)	1	3		
hiatus hernia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)		
occurrences (all)	2	1		
hyperchlorhydria				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	13		
inguinal hernia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	2	1		
irritable bowel syndrome				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
large intestine polyp				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
lip swelling				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	1	0		
mouth ulceration				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)		
occurrences (all)	0	2		
nausea				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	18 / 535 (3.36%)	37 / 1003 (3.69%)		
occurrences (all)	30	51		

oesophageal ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
oesophagitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
oral disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
oral pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pancreatitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
paraesthesia oral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
periodontal disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
rectal polyp			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
stomatitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tongue disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
toothache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	22 / 1003 (2.19%)	
occurrences (all)	3	27	
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	16 / 535 (2.99%)	35 / 1003 (3.49%)	
occurrences (all)	21	49	
Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	
biliary dyskinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cholecystitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	4 / 1003 (0.40%)	
occurrences (all)	3	4	
hepatic steatosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	7 / 1003 (0.70%)	
occurrences (all)	1	7	
hepatomegaly			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hypertransaminasaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
post cholecystectomy syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
actinic keratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
alopecia areata			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
blister				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)		
occurrences (all)	2	0		
blood blister				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	1	1		
cold sweat				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)		
occurrences (all)	4	0		
cutaneous sarcoidosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
dandruff				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
decubitus ulcer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
dermal cyst				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)		
occurrences (all)	0	3		
dermatitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)		
occurrences (all)	3	9		

dermatitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	3 / 1003 (0.30%)	
occurrences (all)	3	3	
dermatitis atopic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
dermatitis contact			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
diabetic foot			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
drug eruption			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
dry skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)	
occurrences (all)	0	6	
eczema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	4 / 1003 (0.40%)	
occurrences (all)	4	4	
eczema nummular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	3	
erythema			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	1	7	
hand dermatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	3	
hidradenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	2 / 1003 (0.20%)	
occurrences (all)	4	2	
hyperkeratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
ingrowing nail			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	2	
ingrown hair			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
lentigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
lichen sclerosus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	

lipodystrophy acquired			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
lipohypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	21 / 1003 (2.09%)	
occurrences (all)	2	22	
macule			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
nail disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
neurodermatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
night sweats			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
panniculitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
papule			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pemphigus			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pigmentation disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
precancerous skin lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)	
occurrences (all)	4	7	
pruritus allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pruritus generalised			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	5	3	
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 535 (1.31%)	24 / 1003 (2.39%)	
occurrences (all)	8	27	
rash erythematous			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	

rash generalised			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
rash macular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
rash pruritic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
rosacea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
sebaceous hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
seborrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
skin burning sensation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
skin discolouration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
skin exfoliation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
skin fissures				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)		
occurrences (all)	1	2		
skin hypertrophy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)		
occurrences (all)	0	2		
skin induration				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	1	0		
skin irritation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	1	1		
skin lesion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)		
occurrences (all)	0	2		
skin mass				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
skin odour abnormal				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	1	1		
skin ulcer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 535 (0.56%)	4 / 1003 (0.40%)		
occurrences (all)	3	5		

telangiectasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
urticaria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	3 / 1003 (0.30%)	
occurrences (all)	3	4	
Renal and urinary disorders			
bladder diverticulum			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
bladder irritation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
bladder prolapse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
diabetic nephropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
dysuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	1	5	
haematuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
hypertonic bladder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	1	1		
micturition disorder				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
micturition urgency				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
nephritic syndrome				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	1	0		
nephrolithiasis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	8 / 535 (1.50%)	8 / 1003 (0.80%)		
occurrences (all)	9	10		
nephropathy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
nocturia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)		
occurrences (all)	2	2		
pollakiuria				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)		
occurrences (all)	1	3		
proteinuria				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)		
occurrences (all)	0	4		

renal colic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
renal cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	4	1	
renal failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
renal failure chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
renal impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
renal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
urinary hesitation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
urinary tract disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
urinary tract obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
urinary tract pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
urine flow decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
urine odour abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hyperthyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
toxic nodular goitre			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	20 / 535 (3.74%)	52 / 1003 (5.18%)	
occurrences (all)	47	68	
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	8 / 1003 (0.80%)	
occurrences (all)	4	9	
arthropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	36 / 535 (6.73%)	70 / 1003 (6.98%)	
occurrences (all)	47	89	
bone loss			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
bone pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
bursitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	5 / 1003 (0.50%)	
occurrences (all)	2	5	
chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
chondropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
costochondritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
facet joint syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
fibromyalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
flank pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)	
occurrences (all)	3	0	
gouty arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
intervertebral disc degeneration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
intervertebral disc disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	

intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
joint stiffness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
joint swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
ligament pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
metatarsalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
muscle contracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
muscle spasms			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	9 / 535 (1.68%)	21 / 1003 (2.09%)	
occurrences (all)	9	21	
muscle swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
muscular weakness			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)		
occurrences (all)	0	2		
musculoskeletal chest pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)		
occurrences (all)	1	5		
musculoskeletal pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	16 / 535 (2.99%)	22 / 1003 (2.19%)		
occurrences (all)	16	24		
musculoskeletal stiffness				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)		
occurrences (all)	4	2		
myalgia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	4 / 535 (0.75%)	18 / 1003 (1.79%)		
occurrences (all)	6	26		
myosclerosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
myositis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
neck pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)		
occurrences (all)	4	7		
neuropathic arthropathy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences (all)	3	0		

osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 535 (1.87%)	14 / 1003 (1.40%)	
occurrences (all)	11	15	
osteochondrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	25 / 535 (4.67%)	42 / 1003 (4.19%)	
occurrences (all)	36	50	
pain in jaw			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
periarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	2	
plantar fasciitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
polyarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	3	
rotator cuff syndrome			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	1	6	
scoliosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
spinal column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
spinal disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
spondylitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
synovial cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
temporomandibular joint syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	5 / 1003 (0.50%)	
occurrences (all)	2	5	

trigger finger			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
abscess jaw			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
abscess limb			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	4	
abscess neck			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
acne pustular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
acute sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
acute tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
anal abscess			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
body tinea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
breast cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	24 / 535 (4.49%)	52 / 1003 (5.18%)	
occurrences (all)	26	60	
bronchitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
bronchitis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
bronchopneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
campylobacter infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	

candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
carbuncle			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	9 / 1003 (0.90%)	
occurrences (all)	6	9	
chronic hepatitis b			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
chronic sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
conjunctivitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
conjunctivitis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)	
occurrences (all)	4	12	
diverticulitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	6 / 1003 (0.60%)	
occurrences (all)	1	6	
ear infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)	
occurrences (all)	4	10	
enterovirus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
erysipelas			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
eye infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
eye infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
folliculitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
fungal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	2	5	
fungal skin infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	

furuncle			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
gangrene			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gardnerella infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 535 (1.50%)	13 / 1003 (1.30%)	
occurrences (all)	8	14	
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 535 (1.50%)	15 / 1003 (1.50%)	
occurrences (all)	8	20	
gastrointestinal viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
genital infection fungal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
gingival infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
gingivitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	1	1		
helicobacter infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)		
occurrences (all)	2	3		
hepatitis c				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
hepatitis e				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
herpes simplex				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
herpes virus infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
herpes zoster				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	6 / 535 (1.12%)	7 / 1003 (0.70%)		
occurrences (all)	6	8		
hordeolum				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences (all)	0	1		
incision site infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences (all)	1	1		

infected dermal cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	2	
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	28 / 535 (5.23%)	59 / 1003 (5.88%)	
occurrences (all)	35	68	
injection site cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
kidney infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
labyrinthitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
laryngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences (all)	0	5	
lobar pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
localised infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	4 / 1003 (0.40%)	
occurrences (all)	5	4	
lower respiratory tract infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	5 / 535 (0.93%)	11 / 1003 (1.10%)	
occurrences (all)	5	14	
measles			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
nail infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	82 / 535 (15.33%)	141 / 1003 (14.06%)	
occurrences (all)	122	196	
nematodiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
onychomycosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	6 / 1003 (0.60%)	
occurrences (all)	2	6	
oral candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
oral herpes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)	
occurrences (all)	4	3	
otitis externa			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	1	4	

otitis media			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
otitis media acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
paronychia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
parotitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
penile infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
periodontitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	14 / 1003 (1.40%)	
occurrences (all)	7	18	
pharyngitis streptococcal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	2	
pharyngotonsillitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
pilonidal cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	10 / 1003 (1.00%)	
occurrences (all)	2	11	
post procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
prostate infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pyelonephritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pyelonephritis acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)	
occurrences (all)	3	6	

respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
rhinitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 535 (1.50%)	5 / 1003 (0.50%)	
occurrences (all)	10	6	
rhinovirus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	4	
sialoadenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	16 / 535 (2.99%)	38 / 1003 (3.79%)	
occurrences (all)	17	51	
sinusitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
skin candida			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
small intestinal bacterial overgrowth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
tinea cruris			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tinea infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tinea pedis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences (all)	0	6	
tinea versicolour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	3	3	
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	12 / 1003 (1.20%)	
occurrences (all)	2	13	
tooth infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)	
occurrences (all)	3	10	
tracheitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	

tracheobronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
tuberculosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	33 / 535 (6.17%)	83 / 1003 (8.28%)	
occurrences (all)	48	119	
urethritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	22 / 535 (4.11%)	47 / 1003 (4.69%)	
occurrences (all)	28	57	
viraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	12 / 1003 (1.20%)	
occurrences (all)	7	12	
viral rhinitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
viral tonsillitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	1	4	
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
yersinia infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
abnormal loss of weight			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
abnormal weight gain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	3	4	
decreased appetite			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
dehydration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
dyslipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	5 / 1003 (0.50%)	
occurrences (all)	6	5	
fluid retention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
food craving			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
gout			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	8 / 1003 (0.80%)	
occurrences (all)	1	9	
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
hyperkalaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)	
occurrences (all)	4	0	

hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
hypertriglyceridaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)	
occurrences (all)	0	6	
hyperuricaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
hypoalbuminaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
hypokalaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
increased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)	
occurrences (all)	0	6	
iron deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
obesity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vitamin b12 deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)	
occurrences (all)	3	6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported