Clinical trial results:
The Impact of LY2605541 versus Insulin Glargine for Patients with Type 1 Diabetes Mellitus Treated with Preprandial Insulin Lispro: a Double-Blind, Randomized, 52-week Study

Summary

EudraCT number	2011-001253-82
Trial protocol	SE GB LT BE ES IE DK GR NL SI
Global end of trial date	03 February 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-BIAO

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01454284
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12147

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 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	03 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is:
• To compare blood sugar control on LY2605541 with insulin glargine after 52 weeks of treatment.
• To compare the rate of nocturnal low blood sugar episodes on LY2605541 with insulin glargine during 52 weeks of treatment.
• To compare the number of participants on LY2605541 reaching blood sugar targets without low blood sugar episodes at night to those taking insulin glargine after 52 weeks of treatment.
• To compare the rate of low blood sugar episodes on LY2605541 with insulin glargine during 52 weeks of treatment

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	11 January 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 572
Country: Number of subjects enrolled	Slovakia: 10
Country: Number of subjects enrolled	Greece: 23
Country: Number of subjects enrolled	Spain: 74
Country: Number of subjects enrolled	Ireland: 5
Country: Number of subjects enrolled	Lithuania: 7
Country: Number of subjects enrolled	Israel: 22
Country: Number of subjects enrolled	United Kingdom: 63
Country: Number of subjects enrolled	France: 19
Country: Number of subjects enrolled	Canada: 52
Country: Number of subjects enrolled	Belgium: 36
Country: Number of subjects enrolled	Brazil: 30
Country: Number of subjects enrolled	Poland: 84
Country: Number of subjects enrolled	Croatia: 10
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	Australia: 39

Country: Number of subjects enrolled	South Africa: 24
Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	New Zealand: 14
Country: Number of subjects enrolled	Sweden: 26
Worldwide total number of subjects	1114
EEA total number of subjects	361

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)	1055
From 65 to 84 years	59
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

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 + Insulin Lispro

Arm description:

Includes participants randomized to receive LY2605541 plus Insulin Lispro.

Participant-specific dose of LY2605541 was administered subcutaneously (SC) once daily at bedtime for 52 weeks.

Participant-specific dose of Insulin Lispro was administered SC at meal times for 52 weeks.

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

Dosage and administration details:

Participant-specific dose of LY2605541 was administered subcutaneously (SC) once daily for 52 weeks.

Investigational medicinal product name	INSULIN LISPRO
Investigational medicinal product code	
Other name	Humalog
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participant-specific dose of Insulin Lispro was administered through Subcutaneous route for 52 weeks.

Arm title	Insulin Glargine + Insulin Lispro

Arm description:

Includes participants randomized to receive Insulin Glargine plus Insulin Lispro.

Participant-specific dose of Insulin Glargine was administered SC once daily at bedtime for 52 weeks.

Participant-specific dose of Insulin Lispro was administered SC at meal times for 52 weeks.

Arm type	Active comparator
Investigational medicinal product name	Insulin Glargine
Investigational medicinal product code	
Other name	Lantus
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:	
Participant-specific dose of Insulin Glargine was administered Subcutaneously for 52 weeks.	
Investigational medicinal product name	Insulin Lispro
Investigational medicinal product code	
Other name	Humalog
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participant-specific dose of Insulin Lispro was administered through Subcutaneous route for 52 weeks.

Number of subjects in period 1	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro
Started	664	450
Received at Least 1 Dose of Study Drug	663	449
Completed	548	377
Not completed	116	73
Adverse event, serious fatal	-	3
Consent withdrawn by subject	58	36
Physician decision	16	11
Adverse event, non-fatal	20	7
Sponsor Decision	-	2
Lost to follow-up	13	8
Protocol deviation	9	6

Baseline characteristics

Reporting groups	
Reporting group title	LY2605541 + Insulin Lispro

Reporting group description:

Includes participants randomized to receive LY2605541 plus Insulin Lispro.

Participant-specific dose of LY2605541 was administered subcutaneously (SC) once daily at bedtime for 52 weeks.

Participant-specific dose of Insulin Lispro was administered SC at meal times for 52 weeks.

Reporting group title	Insulin Glargine + Insulin Lispro

Reporting group description:

Includes participants randomized to receive Insulin Glargine plus Insulin Lispro.

Participant-specific dose of Insulin Glargine was administered SC once daily at bedtime for 52 weeks.

Participant-specific dose of Insulin Lispro was administered SC at meal times for 52 weeks.

Reporting group values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro	Total
Number of subjects	664	450	1114
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	41.58	42.28	
standard deviation	± 13.5	± 13.16	-
Gender, Male/Female Units:			
Female	267	169	436
Male	397	281	678
Region of Enrollment Units: Subjects			
United States	343	229	572
Slovakia	5	5	10
Greece	15	8	23
Spain	44	30	74
Ireland	2	3	5
Lithuania	2	5	7
Israel	13	9	22
United Kingdom	38	25	63
France	12	7	19
Canada	33	19	52
Belgium	20	16	36
Brazil	19	11	30
Poland	51	33	84
Croatia	5	5	10
Denmark	0	1	1
Australia	22	17	39
South Africa	16	8	24

Netherlands	2	1	3
New Zealand	9	5	14
Sweden	13	13	26
Race Units: Subjects			
American Indian or Alaska Native	2	2	4
Asian	6	2	8
Native Hawaiian or Other Pacific Islander	1	0	1
Black or African American	15	14	29
White	625	426	1051
More than one race	15	6	21
Ethnicity Units: Subjects			
Hispanic or Latino	23	18	41
Not Hispanic or Latino	477	315	792
Unknown or Not Reported	164	117	281

End points

End points reporting groups

Reporting group title	LY2605541 + Insulin Lispro

Reporting group description:

Includes participants randomized to receive LY2605541 plus Insulin Lispro.

Participant-specific dose of LY2605541 was administered subcutaneously (SC) once daily at bedtime for 52 weeks.

Participant-specific dose of Insulin Lispro was administered SC at meal times for 52 weeks.

Reporting group title	Insulin Glargine + Insulin Lispro

Reporting group description:

Includes participants randomized to receive Insulin Glargine plus Insulin Lispro.

Participant-specific dose of Insulin Glargine was administered SC once daily at bedtime for 52 weeks.

Participant-specific dose of Insulin Lispro was administered SC at meal times for 52 weeks.

Primary: Hemoglobin A1c (HbA1c)

End point title	Hemoglobin A1c (HbA1c)

End point description:

HbA1c is a test that measures a participant's average blood glucose level over a 2 to 3 month timeframe. Least squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, stratification factors (country, baseline low density lipoprotein cholesterol [LDL-C] [<100 milligrams/deciliter (mg/dL) (2.6 millimoles/liter [mmol/L]) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline HbA1c as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable HbA1c data at both baseline and post-baseline.

End point type	Primary

End point timeframe:

52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	648	444		
Units: percentage of HbA1c				
least squares mean (standard error)	7.38 (± 0.03)	7.61 (± 0.04)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	LY2605541 + Insulin Lispro v Insulin Glargine + Insulin Lispro

Number of subjects included in analysis	1092
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)

Secondary: Hemoglobin A1c (HbA1c)

End point title	Hemoglobin A1c (HbA1c)

End point description:

HbA1c is a test that measures a participant's average blood glucose level over the past 2 to 3 months. LS means were calculated using MMRM adjusting for treatment, stratification factors (country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline HbA1c as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable HbA1c data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	648	444		
Units: percentage of HbA1c				
least squares mean (standard error)	7.09 (± 0.03)	7.42 (± 0.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 weeks in HbA1c

End point title	Change from baseline to 52 weeks in HbA1c

End point description:

HbA1c is a test that measures a participant's average blood glucose level over a 2 to 3 month timeframe. LS means were calculated using MMRM adjusting for treatment, stratification factors (country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline HbA1c as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable HbA1c data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	648	444		
Units: percentage of HbA1c				
least squares mean (standard error)	-0.46 (± 0.03)	-0.24 (± 0.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Total hypoglycemia events

End point title	Total hypoglycemia events

End point description:

Hypoglycemic episodes are defined as events which are associated with reported signs and symptoms of hypoglycemia and/or documented blood glucose (BG) concentrations of ≤70 mg/dL (3.9 mmol/L). Group mean rates of total hypoglycemia (per 30 days) are presented and were calculated from negative binomial regression models (number of episodes = treatment + baseline total hypoglycemia rate, with log [exposure in days/30] as an offset variable). Group mean is estimated by taking the inverse link function on individual participant covariates first and then averages over all participants.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

Baseline through 26 weeks, Baseline through 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	662	449		
Units: episodes/participant/30 days				
arithmetic mean (standard error)				
Weeks 0-26	16.83 (± 0.36)	14.66 (± 0.36)		
Weeks 0-52	15.34 (± 0.32)	13.88 (± 0.35)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with total hypoglycemic events

End point title	Percentage of participants with total hypoglycemic events

End point description:

Hypoglycemic episodes are defined as events that are associated with the reported signs and symptoms of hypoglycemia and/or documented BG concentrations of ≤70 mg/dL (3.9 mmol/L). The percentage of participants was calculated by dividing the number of participants with hypoglycemic episodes by the total number of participants analyzed, multiplied by 100.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

Baseline through 26 weeks, Baseline through 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	662	449		
Units: percentage of participants				
number (not applicable)				
Weeks 0-26	99.1	99.3		
Weeks 0-52	99.2	99.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with HbA1c equal to or less than 6.5% and less than 7.0%

End point title	Percentage of participants with HbA1c equal to 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.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable HbA1c 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 26 weeks, up to 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	648	444		
Units: percentage of participants				
number (not applicable)				
HbA1c ≤6.5%, Week 26	29.6	17.8		
HbA1c ≤6.5%, Week 52	20.8	15.1		
HbA1c <7.0%, Week 26	45.1	34.5		
HbA1c <7.0%, Week 52	35.3	26.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with HbA1c less than 7.0% and without nocturnal hypoglycemia

End point title	Percentage of participants with HbA1c less than 7.0% and without nocturnal hypoglycemia

End point description:

Hypoglycemic episodes are defined as events associated with reported signs and symptoms of hypoglycemia and/or a documented blood glucose concentration of ≤70 mg/dL (3.9 mmol/L). A nocturnal hypoglycemic event occurred between bedtime and waking and between the time points of 10:00 PM and 10:00 AM. The percentage of participants was calculated by dividing the number of participants with HbA1c <7.0% without nocturnal hypoglycemia by the total number of participants analyzed, multiplied by 100.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable data. Missing endpoints were imputed with the LOCF method, using only post-baseline data.

End point type	Secondary

End point timeframe:

up to 26 weeks, up to 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	648	444		
Units: percentage of participants				
number (not applicable)				
Week 26	7.1	1.8		
Week 52	4.3	1.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Nocturnal Hypoglycemia Rates

End point title	Nocturnal Hypoglycemia Rates

End point description:

Hypoglycemic episodes are defined as events that are associated with reported signs and symptoms of hypoglycemia and/or a documented BG concentration of ≤70 mg/dL (3.9 mmol/L). A nocturnal hypoglycemic event occurred between bedtime and waking and between the time points of 10:00 PM and 10:00 AM. Group mean rates of nocturnal hypoglycemia (per 30 days) are presented and were calculated from negative binomial regression models (number of episodes = treatment + baseline nocturnal hypoglycemia rate, with log [exposure in days/30] as an offset variable). Group mean is estimated by taking the inverse link function on individual participant covariates first and then averages over all participants.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

Baseline through 26 weeks, Baseline through 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	662	449		
Units: events/participant/30 days				
arithmetic mean (standard error)				
Weeks 0-26	1.37 (± 0.07)	2.7 (± 0.12)		
Weeks 0-52	1.31 (± 0.06)	2.46 (± 0.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with nocturnal hypoglycemic events

End point title	Percentage of participants with nocturnal hypoglycemic events

End point description:

Hypoglycemic episodes are defined as events associated with the reported signs and symptoms of hypoglycemia and/or a BG concentration of ≤70 mg/dL (3.9 mmol/L). A nocturnal hypoglycemic event occurred between bedtime and waking and between the time points of 10:00 PM and 10:00 AM. The percentage of participants was calculated by dividing the number of participants with nocturnal hypoglycemic episodes by the total number of participants analyzed, multiplied by 100.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

Baseline through 26 weeks, Baseline through 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	662	449		
Units: percentage of participants				
number (not applicable)				
Weeks 0-26	81.7	94.7		
Weeks 0-52	87.5	96.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in body weight

End point title	Change in body weight

End point description:

LS means were calculated using MMRM adjusting for treatment, stratification factors (baseline HbA1c [≤8.5% and >8.5%], country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline body weight as fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable body weight data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

Baseline, 26 weeks, 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	648	439		
Units: kilograms (kg)				
least squares mean (standard error)				
Week 26	-0.55 (± 0.14)	0.78 (± 0.16)		
Week 52	-0.61 (± 0.17)	1.21 (± 0.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: 9 point self-monitored blood glucose (SMBG)

End point title	9 point self-monitored blood glucose (SMBG)

End point description:

9-point SMBG profiles were obtained over 2 days within the week prior to Weeks 0, 4, 12, 26, 39, and 52. SMBG measurements were taken at 9 time points: pre-morning meal, 2 hours post-morning meal, pre-midday meal, 2 hours post-midday meal, pre-evening meal, 2 hours post-evening meal, bedtime, at approximately 0300 hours, and the subsequent morning prior to the morning meal. LS means were calculated using MMRM adjusting for treatment, stratification factors (baseline HbA1c [≤8.5% and >8.5%], country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline BG values as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable SMBG data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	615	416		
Units: mg/dL				
least squares mean (standard error)				
Pre-morning meal, Week 26 (n=615, 416)	153.85 (± 2.67)	148.91 (± 3.17)		
Pre-morning meal, Week 52 (n=615, 416)	156.18 (± 2.75)	155.25 (± 3.3)		
2 hour post-morning meal, Week 26 (n=572, 380)	164.59 (± 3.44)	178.47 (± 4.07)		
2 hour post-morning meal, Week 52 (n=572, 380)	171.94 (± 3.43)	183.35 (± 4.1)		
Pre-midday meal, Week 26 (n=611, 403)	136.7 (± 2.7)	152.87 (± 3.22)		
Pre-midday meal, Week 52 (n=611, 403)	145.22 (± 2.87)	158.5 (± 3.42)		
2 hour post-midday meal, Week 26 (n=579, 379)	150.66 (± 3.32)	164.47 (± 3.94)		
2 hour post-midday meal, Week 52 (n=579, 379)	156.92 (± 3.73)	172.61 (± 4.42)		
Pre-evening meal, Week 26 (n=603, 407)	155.38 (± 3.13)	176.5 (± 3.73)		
Pre-evening meal, Week 52 (n=603, 407)	153.3 (± 3.21)	170.83 (± 3.79)		
2 hour post-evening meal, Week 26 (n=559, 373)	160.5 (± 3.85)	181.18 (± 4.54)		
2 hour post-evening meal, Week 52 (n=559, 373)	169.61 (± 4.19)	184.19 (± 4.99)		
Bedtime, Week 26 (n=578, 382)	163.9 (± 3.24)	180.97 (± 3.84)		
Bedtime, Week 52 (n=578, 382)	168.04 (± 3.58)	187.09 (± 4.3)		
0300 Hours, Week 26 (n=529, 347)	169.64 (± 3.69)	163.09 (± 4.39)		
0300 Hours, Week 52 (n=529, 347)	168.72 (± 3.94)	174.11 (± 4.72)		
Pre-morning meal next day, Week 26 (n=583, 403)	150.04 (± 2.76)	145.77 (± 3.23)		

Pre-morning meal next day, Week 52 (n=583, 403)	151.22 (± 2.7)	149.56 (± 3.2)		

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:

Fasting serum glucose (FSG) is measured in blood before the morning meal. LS means were calculated using MMRM adjusting for treatment, stratification factors (baseline HbA1c [≤8.5% and >8.5%], country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline HbA1c as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable FSG data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	646	443		
Units: mg/dL				
least squares mean (standard error)				
Week 26	139.76 (± 2.75)	155.23 (± 3.25)		
Week 52	142.02 (± 2.95)	171.67 (± 3.48)		

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:

Fasting blood glucose (FBG) was measured by SMBG pre-morning meal. LS means were calculated using MMRM adjusting for treatment, stratification factors (baseline HbA1c [≤8.5% and >8.5%], country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline FBG as the

fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable FBG data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	643	441		
Units: mg/dL				
least squares mean (standard error)				
Week 26	154.84 (± 1.96)	151.46 (± 2.31)		
Week 52	159.85 (± 2.02)	153.09 (± 2.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-participant variability of fasting blood glucose (FBG)

End point title	Intra-participant variability of fasting blood glucose (FBG)

End point description:

FBG was measured by SMBG. Between-day glucose variability is measured by the standard deviation (SD) of FBG. LS means were calculated using MMRM adjusting for treatment, stratification factors (baseline HbA1c [≤8.5% and >8.5%], country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline SD of FBG as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable FBG data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	639	437		
Units: mg/dL				
least squares mean (standard error)				
Week 26	51.7 (± 1.22)	64.73 (± 1.44)		

Week 52	53.97 (± 1.24)	63.11 (± 1.46)		

Statistical analyses

No statistical analyses for this end point

Secondary: 0300 hours blood glucose (BG) to fasting BG excursion

End point title	0300 hours blood glucose (BG) to fasting BG excursion

End point description:

Results of a 0300-hour to pre-morning meal (FBG) excursion are presented (only excursions within a single SMBG profile are included). LS means were calculated using MMRM adjusting for treatment, stratification factors (baseline HbA1c [≤8.5% and >8.5%], country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], baseline prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment-by-visit interaction, and baseline excursion as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable SMBG data at baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	498	332		
Units: mg/dL				
least squares mean (standard error)				
Week 26	-25.49 (± 3.96)	-16.44 (± 4.72)		
Week 52	-23.36 (± 4.1)	-29.01 (± 4.87)		

Statistical analyses

No statistical analyses for this end point

Secondary: Triglycerides, low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), and total cholesterol

End point title	Triglycerides, low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), and total cholesterol

End point description:

Concentrations of cholesterol, HDL-C, and LDL-C, and triglycerides are presented. LS means were calculated using MMRM adjusting for stratification factors (baseline HbA1c [≤8.5% and >8.5%], country, LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L), except for the LDL-C

outcome variable], prior basal insulin therapy [insulin glargine/detemir/other]), visit, treatment, treatment-by-visit interaction, and baseline value of corresponding lipid outcome variable as the fixed effects and participant as a random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable lipid data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	650	446		
Units: mg/dL				
least squares mean (standard error)				
Cholesterol, Week 26	185.51 (± 1.09)	179.3 (± 1.29)		
Cholesterol, Week 52	184.66 (± 1.13)	178.13 (± 1.34)		
HDL-C, Week 26	58.44 (± 0.39)	61.52 (± 0.46)		
HDL-C, Week 52	58.13 (± 0.39)	59.52 (± 0.46)		
LDL-C, Week 26	106.25 (± 0.9)	100.9 (± 1.07)		
LDL-C, Week 52	105.8 (± 0.96)	101.2 (± 1.14)		
Triglycerides, Week 26	105.26 (± 2.3)	85.11 (± 2.73)		
Triglycerides, Week 52	104.84 (± 2.17)	88.12 (± 2.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Change in anti-LY2605541 antibodies

End point title	Percentage of Participants with Change in anti-LY2605541 antibodies

End point description:

The percentage of participants with anti-LY2605541 treatment-emergent antibody response (TEAR) is summarized. TEAR is defined as change from baseline to post-baseline in the anti-LY2605541 antibody level either from undetectable to detectable, or from detectable to the value with at least 130% relative increase from baseline.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable anti-LY2605541 antibody data at baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks, 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	556	399		
Units: percentage of participants				
number (not applicable)				
Week 26 (n=556, 399)	30.2	14		
Week 52 (n=509, 363)	32.8	10.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Basal, meal time, and total insulin dose per body weight

End point title	Basal, meal time, and total insulin dose per body weight

End point description:

Basal insulin dose, meal-time insulin dose (short-acting bolus dose), and total insulin dose were calculated based on the dose during the last 7 days prior to the post-treatment visit or last 3 days prior to the randomization visit. LS means were calculated using a constrained Longitudinal Data Analysis (cLDA) model adjusting for indicator variables of each treatment group at each postbaseline visit and stratification variables (baseline HbA1c [≤8.5% and> 8.5%], country, baseline LDL-C [<100 mg/dL (2.6 mmol/L) and ≥100 mg/dL (2.6 mmol/L)], and baseline prior basal insulin therapy [insulin glargine/detemir/ other]) as fixed effects.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable insulin dose data.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	551	392		
Units: units/weight/day				
least squares mean (standard error)				
Basal insulin, Week 26 (n=527, 374)	0.46 (± 0.01)	0.35 (± 0.01)		
Basal insulin, Week 52 (n=508, 367)	0.47 (± 0.01)	0.35 (± 0.01)		
Meal time insulin, Week 26 (n=542, 388)	0.32 (± 0.01)	0.44 (± 0.01)		
Meal time insulin, Week 52 (n=490, 352)	0.33 (± 0.01)	0.43 (± 0.01)		
Total insulin, Week 26 (n=551, 392)	0.75 (± 0.01)	0.77 (± 0.01)		
Total insulin, Week 52 (n=509, 369)	0.78 (± 0.01)	0.77 (± 0.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: Insulin Treatment Satisfaction Questionnaire

End point title	Insulin Treatment Satisfaction Questionnaire

End point description:

Insulin Treatment Satisfaction Questionnaire (ITSQ) is a validated measure containing 22 items that assess treatment satisfaction for participants with diabetes and on insulin. The questionnaire measures satisfaction from the following 5 domains: Convenience of Regimen, Lifestyle Flexibility, Glycemic Control, Hypoglycemic Control, and Insulin Delivery Device. Data are transformed to a scale of 0-100, where higher scores indicate better treatment satisfaction. LS means were calculated using an ANCOVA model adjusting for treatment, baseline HbA1c (≤8.5% and >8.5%), country, and baseline prior basal insulin therapy (insulin glargine/detemir/other) as fixed effects and baseline ITSQ scores as a covariate.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable ITSQ data at both baseline and post-baseline. Missing endpoints were imputed with the LOCF method.

End point type	Secondary

End point timeframe:

up to 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	561	406		
Units: units on a scale				
least squares mean (standard error)	73.6 (± 0.57)	72.92 (± 0.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: European Quality of Life -5 dimension (EQ-5D-3L)

End point title	European Quality of Life -5 dimension (EQ-5D-3L)

End point description:

EQ-5D-3L, 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 1-3 (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 an ANCOVA adjusting for treatment, baseline HbA1c (≤8.5% and >8.5%), country, baseline prior basal insulin therapy (insulin glargine/detemir/other), and baseline EQ-5D-3L score as covariates.
Analysis Population Description:Participants who were randomized, had at least 1 dose of study medication, and had evaluable EQ-5D-3L data at both baseline and post-baseline. Missing endpoints were imputed with the LOCF method.

End point type	Secondary

End point timeframe:

up to 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	566	406		
Units: units on a scale				
least squares mean (standard error)	0.91 (± 0)	0.92 (± 0.01)		

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:

Low Blood Sugar Survey (LBSS) (also referenced as Hypoglycemia Fear Survey – II [HFS-II]) is a questionnaire that measures 1) behaviors to avoid hypoglycemia and its negative consequences (15 items) and 2) worries about hypoglycemia and its negative consequences (18 items). Responses are made on a 5-point Likert-type scale where 0 = Never and 4 = Always. Total score is the sum of all items (range 0-132). Higher total scores reflect greater fear of hypoglycemia. LS means were calculated using MMRM adjusting for treatment, baseline HbA1c (≤8.5% and >8.5%), country, baseline prior basal insulin therapy (insulin glargine/detemir/other), visit, treatment-by-visit interaction, and baseline LBSS score as the fixed effects and participant as the random effect.

Analysis Population Description: Participants who were randomized, had at least 1 dose of study medication, and had evaluable LBSS data at both baseline and post-baseline.

End point type	Secondary

End point timeframe:

26 weeks and 52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	657	447		
Units: units on a scale				
least squares mean (standard error)				
Week 26	29.48 (± 0.55)	29.12 (± 0.65)		
Week 52	30.43 (± 0.59)	29.27 (± 0.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Rapid Assessment of Physical Activity (RAPA)

End point title	Rapid Assessment of Physical Activity (RAPA)

End point description:

RAPA assesses the level and intensity of physical activity of adult participants. It contains 2 subscales: 1 (Aerobic) and 2 (Strength and Flexibility). RAPA 1 contains 7 questions regarding the participant's amount and intensity of physical activity, allowing each participant's aerobic activity level to be categorized as sedentary, underactive, light activity, regular underactive, or active. RAPA 2 contains 2 questions regarding participants' physical activities that increase strength and improve flexibility. Each participant's strength and flexibility activity level is then categorized as neither strength nor flexible, either strength or flexible (not both), both strength and flexible. The % of participants in each RAPA 1/2 category was calculated by dividing the number of participants in each RAPA 1/2 category by the total number of participants analyzed, multiplied by 100.
Participants who were randomized, had at least 1 dose of study medication, and had evaluable RAPA data.

End point type	Secondary

End point timeframe:

52 weeks

End point values	LY2605541 + Insulin Lispro	Insulin Glargine + Insulin Lispro		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	367	254		
Units: percentage of participants				
number (not applicable)				
RAPA 1, Sedentary (n=364, 249)	1.1	1.2		
RAPA 1, Underactive (n=364, 249)	3.8	4.8		
RAPA 1, Light activity (n=364, 249)	13.7	14.5		
RAPA 1, Regular underactive (n=364, 249)	24.5	28.5		
RAPA 1, Active (n=364, 249)	56.9	51		
RAPA 2, Neither strength/flexibility (n=367, 254)	39	46.9		
RAPA 2, Either strength/flexibility (n=367, 254)	28.9	26.8		
RAPA 2, Both strength/flexibility (n=367, 254)	32.2	26.4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Analysis Period 2 (AP2)	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.0
Reporting groups	
Reporting group title	Glargine + Insulin Lispro
Reporting group description: -	
Reporting group title	LY2605541 + Insulin Lispro
Reporting group description: -	

Serious adverse events	Glargine + Insulin Lispro	LY2605541 + Insulin Lispro	
Total subjects affected by serious adverse events			
subjects affected / exposed	92 / 449 (20.49%)	117 / 663 (17.65%)	
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 gastric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
benign hydatidiform mole			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

bladder papilloma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebellopontine angle tumour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (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 metastatic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma of the tongue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
hyperemesis gravidarum			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (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			
drug hypersensitivity			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
food allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
ovarian cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleural effusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory distress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			

acute psychosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
major depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
weight decreased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
accident at home			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
eye injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (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	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
femur fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gun shot wound			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
hand fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intentional overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rib fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
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 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
thermal burn			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tibia fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

upper limb fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
wrist fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (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 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina pectoris			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina unstable			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
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 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac failure			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery occlusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
convulsion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
epilepsy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemic seizure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemic unconsciousness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient global amnesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

transient ischaemic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
autoimmune thrombocytopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphadenopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
colitis microscopic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
enteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric ulcer			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
drug-induced liver injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
eczema			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lipohypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
skin ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urticaria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
nephrotic syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (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 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuropathic arthropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abscess oral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendicitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
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 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lobar pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteomyelitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyelonephritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

sepsis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
viraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
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 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic ketoacidosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 449 (1.34%)	3 / 663 (0.45%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences causally related to treatment / all	2 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	58 / 449 (12.92%)	71 / 663 (10.71%)	
occurrences causally related to treatment / all	81 / 95	84 / 108	
deaths causally related to treatment / all	0 / 0	0 / 0	
ketoacidosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Glargine + Insulin Lispro	LY2605541 + Insulin Lispro	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	305 / 449 (67.93%)	502 / 663 (75.72%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
haemangioma of liver			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
lip neoplasm benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
lipoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	2	2	
malignant melanoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
melanocytic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	

prostatic adenoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
skin papilloma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Vascular disorders			
aortic stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
arterial occlusive disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
arteriosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
flushing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
hypertension			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	11 / 449 (2.45%)	11 / 663 (1.66%)	
occurrences (all)	11	12	
intra-abdominal haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
orthostatic hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
phlebitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
spider vein			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
acrochordon excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
artificial crown procedure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
cataract operation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 449 (0.67%)	3 / 663 (0.45%)	
occurrences (all)	4	4	
cholecystectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
circumcision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
coronary artery bypass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
endodontic procedure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
endometrial ablation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
eye laser surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	4	
fasciectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
female sterilisation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	

gastric operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
glaucoma surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hysterectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
intraocular lens implant			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
knee arthroplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
knee operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
limb operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	
micrographic skin surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
mole excision			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
myomectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
oral surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
percutaneous coronary intervention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
peripheral artery bypass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
pilonidal sinus repair			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
plastic surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
plastic surgery to the face			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
pleurodesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	

removal of foreign body from joint			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
shoulder operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
tendon sheath incision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
tendon sheath lesion excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
thoracotomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
tonsillectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
tooth extraction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	4 / 663 (0.60%)	
occurrences (all)	4	4	
vasectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
wisdom teeth removal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
General disorders and administration site conditions			
application site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
application site pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	3 / 663 (0.45%)	
occurrences (all)	3	3	
atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
chest discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
chills			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
early satiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
fat tissue increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
fatigue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 449 (1.78%)	10 / 663 (1.51%)	
occurrences (all)	8	11	
feeling hot			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
feeling jittery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	

hyperthermia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	3	
implant site pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
induration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
inflammatory pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	
influenza like illness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	7 / 663 (1.06%)	
occurrences (all)	6	7	
infusion site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
infusion site hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	3	
injection site atrophy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
injection site bruising			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	3	
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
injection site haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
injection site haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
injection site hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	16 / 663 (2.41%)	
occurrences (all)	0	20	
injection site induration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	3	
injection site inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
injection site mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	3	

injection site oedema				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)		
occurrences (all)	0	4		
injection site pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)		
occurrences (all)	2	0		
injection site reaction				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	5 / 663 (0.75%)		
occurrences (all)	0	5		
injection site swelling				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	13 / 663 (1.96%)		
occurrences (all)	0	15		
local swelling				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
localised oedema				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
malaise				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)		
occurrences (all)	0	3		
mass				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
medical device site reaction				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
nodule			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	13 / 663 (1.96%)	
occurrences (all)	5	17	
pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	2 / 663 (0.30%)	
occurrences (all)	2	2	
puncture site swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 449 (1.78%)	10 / 663 (1.51%)	
occurrences (all)	9	10	
swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	

thrombosis in device			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
vessel puncture site pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Immune system disorders			
allergy to chemicals			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
anaphylactic reaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
food allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
seasonal allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	5 / 663 (0.75%)	
occurrences (all)	2	5	
Reproductive system and breast disorders			
breast mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	4	
breast pain			

alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
diabetic mastopathy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)		
occurrences (all)	1	0		
dysmenorrhoea				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 449 (0.67%)	3 / 663 (0.45%)		
occurrences (all)	3	3		
endometriosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
menopausal symptoms				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
menorrhagia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)		
occurrences (all)	1	1		
menstrual disorder				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)		
occurrences (all)	1	2		
metrorrhagia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)		
occurrences (all)	1	0		
ovarian cyst				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
polycystic ovaries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
prostatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
rectocele			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
scrotal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
vulval disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
atelectasis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	14 / 449 (3.12%)	31 / 663 (4.68%)	
occurrences (all)	15	32	
dysphonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
dyspnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
emphysema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
epistaxis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
increased upper airway secretion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
lung infiltration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
nasal congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	4 / 663 (0.60%)	
occurrences (all)	4	5	

nasal septum deviation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
oropharyngeal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	12 / 449 (2.67%)	14 / 663 (2.11%)	
occurrences (all)	12	15	
productive cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	2 / 663 (0.30%)	
occurrences (all)	3	2	
pulmonary oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
respiratory tract congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	3	
restrictive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
rhinitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	8	
rhinorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
sinus congestion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	4 / 449 (0.89%)	5 / 663 (0.75%)	
occurrences (all)	5	5	
upper respiratory tract congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
upper-airway cough syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
Psychiatric disorders			
abnormal dreams			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
acute psychosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
affective disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
alcoholism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
anxiety			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 449 (0.67%)	8 / 663 (1.21%)	
occurrences (all)	3	8	
anxiety disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
attention deficit/hyperactivity disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
bipolar disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 449 (1.34%)	9 / 663 (1.36%)	
occurrences (all)	6	9	
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 449 (1.34%)	4 / 663 (0.60%)	
occurrences (all)	6	4	
major depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
mood swings			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
premature ejaculation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	

psychotic disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
sleep disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
social phobia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
Hepatobiliary disorders			
cholecystitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
hepatic steatosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	4	
hepatobiliary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hepatotoxicity			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hypertransaminasaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	17 / 663 (2.56%)	
occurrences (all)	4	17	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	7 / 663 (1.06%)	
occurrences (all)	4	7	
biopsy skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	4 / 663 (0.60%)	
occurrences (all)	0	4	
blood bilirubin increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	0 / 663 (0.00%)	
occurrences (all)	6	0	
blood cholesterol increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 449 (0.67%)	5 / 663 (0.75%)	
occurrences (all)	4	5	
blood culture positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
blood glucose abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
blood potassium increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
blood testosterone decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
blood thyroid stimulating hormone decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
blood triglycerides increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
cardiac murmur			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	

carotid bruit				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
catheterisation cardiac				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)		
occurrences (all)	1	0		
colonoscopy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)		
occurrences (all)	0	2		
haematocrit increased				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
haemoglobin increased				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
heart rate irregular				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)		
occurrences (all)	1	1		
hepatic enzyme increased				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 449 (0.67%)	9 / 663 (1.36%)		
occurrences (all)	3	10		
liver function test abnormal				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	5 / 449 (1.11%)	8 / 663 (1.21%)		
occurrences (all)	5	8		
pregnancy test positive				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
prostatic specific antigen increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
protein urine present			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	4 / 663 (0.60%)	
occurrences (all)	2	4	
transaminases increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	4	
troponin increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
urine ketone body present			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
vitamin d decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
weight decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	8 / 663 (1.21%)	
occurrences (all)	5	8	
weight increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 449 (1.34%)	15 / 663 (2.26%)	
occurrences (all)	6	16	

white blood cell count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
white blood cells urine positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	3	
ankle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
arthropod bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
arthropod sting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
back injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
cartilage injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
clavicle fracture			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
concussion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	8 / 663 (1.21%)	
occurrences (all)	2	9	
corneal abrasion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
epicondylitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
excoriation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	4	
face injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
facial bones fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
fall			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 449 (0.45%)	2 / 663 (0.30%)	
occurrences (all)	2	2	
fascial rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	4 / 663 (0.60%)	
occurrences (all)	3	4	
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
humerus fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
joint dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
joint injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	2	
laceration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	5 / 663 (0.75%)	
occurrences (all)	2	6	

ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	7 / 663 (1.06%)	
occurrences (all)	4	9	
limb injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	4 / 663 (0.60%)	
occurrences (all)	2	4	
muscle injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	5 / 663 (0.75%)	
occurrences (all)	3	5	
overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
patella fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
post-traumatic pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	4 / 663 (0.60%)	
occurrences (all)	3	4	
rib fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
road traffic accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
skeletal injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
skin injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
subdural haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
sunburn			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
thermal burn			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	0 / 663 (0.00%)	
occurrences (all)	5	0	
tooth fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	2 / 663 (0.30%)	
occurrences (all)	3	2	
upper limb fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	

wound			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	4 / 663 (0.60%)	
occurrences (all)	2	4	
Congenital, familial and genetic disorders			
phimosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	3	
aortic valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
atrial flutter			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
bundle branch block left			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
cardiac failure congestive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
cardiomegaly			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
mitral valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
mitral valve prolapse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
palpitations			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	3	
sinus bradycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	3 / 663 (0.45%)	
occurrences (all)	2	3	
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
tricuspid valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Nervous system disorders			
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
balance disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
burning sensation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	2 / 663 (0.30%)	
occurrences (all)	2	2	
cerebrospinal fluid leakage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
dementia alzheimer's type			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
diabetic neuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	5 / 663 (0.75%)	
occurrences (all)	2	5	
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	5 / 663 (0.75%)	
occurrences (all)	2	5	
dizziness postural			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	

dysgeusia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	14 / 449 (3.12%)	24 / 663 (3.62%)	
occurrences (all)	21	37	
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	12 / 663 (1.81%)	
occurrences (all)	1	14	
lethargy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
memory impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	8 / 663 (1.21%)	
occurrences (all)	4	9	
nerve compression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
neuralgia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
neuritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
neuropathy peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	4 / 663 (0.60%)	
occurrences (all)	2	5	
occipital neuralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	7 / 663 (1.06%)	
occurrences (all)	6	7	
peroneal nerve palsy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
polyneuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
radicular syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	

restless legs syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
sciatica			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
sinus headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	
tension headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
tremor			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
viith nerve paralysis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	2 / 663 (0.30%)	
occurrences (all)	4	2	
anaemia of chronic disease			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
lymphadenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
lymphadenopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
pernicious anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
auricular swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
cerumen impaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
ear discomfort			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
ear pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
tinnitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	3 / 663 (0.45%)	
occurrences (all)	3	3	
Eye disorders			
abnormal sensation in eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
asthenopia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
blepharitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	4	
conjunctival haemorrhage			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
conjunctival hyperaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
conjunctivitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	2 / 663 (0.30%)	
occurrences (all)	5	2	
diabetic retinopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 449 (1.34%)	5 / 663 (0.75%)	
occurrences (all)	6	6	
eye haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
eye irritation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
eye pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
eye swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
glaucoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	

lacrimation increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
macular oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
ocular hyperaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
pinguecula			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
retinal detachment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
retinal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
retinopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
retinopathy proliferative			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
vision blurred			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 449 (0.45%)	2 / 663 (0.30%)	
occurrences (all)	2	2	
visual impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
vitreous floaters			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
vitreous haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	2 / 663 (0.30%)	
occurrences (all)	2	2	
abdominal distension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	6 / 663 (0.90%)	
occurrences (all)	0	6	
abdominal mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	3	
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	7 / 663 (1.06%)	
occurrences (all)	5	8	
abdominal pain lower			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	7 / 663 (1.06%)	
occurrences (all)	6	7	
aphthous stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
coeliac disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	3	
colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	10 / 663 (1.51%)	
occurrences (all)	3	10	
dental caries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	4	
diabetic gastroparesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	16 / 449 (3.56%)	14 / 663 (2.11%)	
occurrences (all)	17	16	

dry mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	5 / 663 (0.75%)	
occurrences (all)	5	5	
dysphagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
epigastric discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
flatulence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
food poisoning			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
gastric dilatation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
gastric ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
gastritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
gastroduodenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
gastrointestinal disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 449 (1.34%)	6 / 663 (0.90%)	
occurrences (all)	6	6	
gingival bleeding			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
gingival disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
glossodynia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
haematochezia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
hiatus hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	

impaired gastric emptying			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
inguinal hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
lip swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	17 / 449 (3.79%)	21 / 663 (3.17%)	
occurrences (all)	18	27	
odynophagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
oesophagitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
oesophageal achalasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
oral disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)		
occurrences (all)	1	0		
oral pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)		
occurrences (all)	2	1		
paraesthesia oral				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
parotid duct obstruction				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
parotid gland inflammation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
periodontal disease				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)		
occurrences (all)	1	0		
rectal haemorrhage				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
tooth discolouration				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
toothache				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 449 (0.45%)	7 / 663 (1.06%)		
occurrences (all)	2	8		

umbilical hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
uvulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	16 / 449 (3.56%)	20 / 663 (3.02%)	
occurrences (all)	21	20	
Skin and subcutaneous tissue disorders			
actinic keratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	4 / 663 (0.60%)	
occurrences (all)	0	4	
blister			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	0 / 663 (0.00%)	
occurrences (all)	3	0	
dermal cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
dermatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
dermatitis allergic			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
dermatitis atopic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
dermatitis contact			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	4 / 663 (0.60%)	
occurrences (all)	2	4	
diabetic cheiropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
diabetic foot			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
dry skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
ecchymosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	3	
eczema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	

hair texture abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hyperkeratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
hypertrichosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
ingrowing nail			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
lichen planus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
lipoatrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
lipodystrophy acquired			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	8 / 663 (1.21%)	
occurrences (all)	0	10	
lipohypertrophy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	55 / 663 (8.30%)		
occurrences (all)	1	69		
nail disorder				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
night sweats				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
peau d'orange				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
pityriasis rosea				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)		
occurrences (all)	0	2		
precancerous skin lesion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
pruritus				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 449 (0.45%)	6 / 663 (0.90%)		
occurrences (all)	2	7		
pruritus allergic				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
pruritus generalised				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)		
occurrences (all)	1	0		

psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	9 / 663 (1.36%)	
occurrences (all)	4	10	
rash pruritic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
scab			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
skin hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
skin induration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
skin lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
skin mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
skin striae			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
skin ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
urticaria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	5	
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
haematuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	3 / 663 (0.45%)	
occurrences (all)	2	3	
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	2 / 663 (0.30%)	
occurrences (all)	2	2	
proteinuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
renal colic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
renal failure			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
renal failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
renal failure chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
renal impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
urinary retention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Endocrine disorders			
hyperparathyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hypogonadism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
hypothyroidism			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
secondary hypogonadism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 449 (2.23%)	14 / 663 (2.11%)	
occurrences (all)	12	15	
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	3 / 663 (0.45%)	
occurrences (all)	2	4	
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 449 (1.34%)	8 / 663 (1.21%)	
occurrences (all)	7	8	
bone pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
bursitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
chondropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
coccydynia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	
costochondritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
exostosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
fibromyalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
flank pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
gouty arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
groin pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
intervertebral disc space narrowing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	

joint stiffness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
joint swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	3	
lateral patellar compression syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	
lumbar spinal stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
muscle spasms			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	8 / 663 (1.21%)	
occurrences (all)	3	9	
muscular weakness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
musculoskeletal chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	3	
musculoskeletal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 449 (1.78%)	8 / 663 (1.21%)	
occurrences (all)	8	11	
myalgia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	6 / 449 (1.34%)	7 / 663 (1.06%)	
occurrences (all)	7	8	
myositis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
neck pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	5	
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
osteoporosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	12 / 663 (1.81%)	
occurrences (all)	5	12	
pain in jaw			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
periarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
plantar fasciitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	5	

rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
soft tissue disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
spinal column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
synovial cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	3	
tendon disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	2 / 663 (0.30%)	
occurrences (all)	3	2	
tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
torticollis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
trigger finger			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	3	
Infections and infestations			
abscess sweat gland			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
acute sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	4 / 663 (0.60%)	
occurrences (all)	3	4	
acute tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
atypical pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
bacterial infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
body tinea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	3 / 663 (0.45%)	
occurrences (all)	0	3	
borrelia infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
bronchitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	12 / 449 (2.67%)	16 / 663 (2.41%)	
occurrences (all)	14	17	
bronchopneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
burn infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	3 / 663 (0.45%)	
occurrences (all)	4	3	
chlamydial infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
conjunctivitis infective			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
cystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
dengue fever			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	

dermatitis infected			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
ear infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	6 / 663 (0.90%)	
occurrences (all)	4	7	
erythema migrans			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
eye infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
eye infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
folliculitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	5	
fungal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	3 / 663 (0.45%)	
occurrences (all)	5	3	
furuncle			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
gastritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	2	
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	11 / 449 (2.45%)	12 / 663 (1.81%)	
occurrences (all)	14	15	
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	15 / 449 (3.34%)	18 / 663 (2.71%)	
occurrences (all)	15	18	
gingival abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
gingival infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
hepatitis c			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
herpes simplex			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	5 / 663 (0.75%)	
occurrences (all)	4	5	

infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
infectious pleural effusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	22 / 449 (4.90%)	45 / 663 (6.79%)	
occurrences (all)	23	47	
kidney infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
labyrinthitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
laryngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
localised infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	8 / 663 (1.21%)	
occurrences (all)	1	8	
lower respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	6 / 663 (0.90%)	
occurrences (all)	4	6	
mononucleosis syndrome			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
nasal abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	70 / 449 (15.59%)	105 / 663 (15.84%)	
occurrences (all)	99	141	
onychomycosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	3 / 663 (0.45%)	
occurrences (all)	2	3	
oral candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
oral herpes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 449 (0.89%)	2 / 663 (0.30%)	
occurrences (all)	4	2	
otitis externa			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
otitis media			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	1 / 663 (0.15%)	
occurrences (all)	1	1	
paronychia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)	
occurrences (all)	1	2	

pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 449 (1.78%)	6 / 663 (0.90%)	
occurrences (all)	9	6	
pharyngitis streptococcal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	5 / 663 (0.75%)	
occurrences (all)	3	6	
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	2 / 663 (0.30%)	
occurrences (all)	5	2	
post procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
postoperative wound infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	4	
respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
rhinitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	3	
rhinovirus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)	
occurrences (all)	2	1	
rotavirus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	14 / 449 (3.12%)	29 / 663 (4.37%)	
occurrences (all)	19	33	
skin infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	1 / 663 (0.15%)	
occurrences (all)	3	1	
soft tissue infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
staphylococcal skin infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	

syphilis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
tinea cruris			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
tinea pedis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	6 / 663 (0.90%)	
occurrences (all)	1	6	
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 449 (1.11%)	9 / 663 (1.36%)	
occurrences (all)	5	9	
tooth infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	6 / 663 (0.90%)	
occurrences (all)	3	7	
tracheitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
tracheobronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	40 / 449 (8.91%)	61 / 663 (9.20%)	
occurrences (all)	52	76	
urethritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	15 / 449 (3.34%)	24 / 663 (3.62%)	
occurrences (all)	18	28	
vaginal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
vaginitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
viral diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	12 / 449 (2.67%)	7 / 663 (1.06%)	
occurrences (all)	12	9	
viral pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 449 (0.67%)	5 / 663 (0.75%)	
occurrences (all)	3	5	

vulvovaginal candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	4 / 663 (0.60%)	
occurrences (all)	1	4	
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
wound infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
Metabolism and nutrition disorders			
abnormal loss of weight			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
decreased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	5 / 663 (0.75%)	
occurrences (all)	0	5	
decreased insulin requirement			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
dehydration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	2	0	
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
diabetic ketoacidosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
dyslipidaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	2 / 663 (0.30%)		
occurrences (all)	1	2		
fluid retention				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)		
occurrences (all)	1	0		
gout				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 449 (0.45%)	1 / 663 (0.15%)		
occurrences (all)	2	1		
hypercalcaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
hypercholesterolaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	5 / 663 (0.75%)		
occurrences (all)	0	5		
hyperglycaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	5 / 449 (1.11%)	2 / 663 (0.30%)		
occurrences (all)	5	2		
hyperlipidaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)		
occurrences (all)	0	1		
hypertriglyceridaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 449 (0.00%)	5 / 663 (0.75%)		
occurrences (all)	0	6		

hypocalcaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
hypokalaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 449 (0.45%)	0 / 663 (0.00%)	
occurrences (all)	3	0	
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
iron deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	1 / 663 (0.15%)	
occurrences (all)	0	1	
obesity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 449 (0.00%)	2 / 663 (0.30%)	
occurrences (all)	0	2	
overweight			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	0 / 663 (0.00%)	
occurrences (all)	1	0	
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 449 (0.22%)	3 / 663 (0.45%)	
occurrences (all)	1	3	

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