



## 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
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##### 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:

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### **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
<b>Arm title</b>	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.

<b>Arm title</b>	Insulin Glargine + Insulin Lispro
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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.

<b>Number of subjects in period 1</b>	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
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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
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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 standard deviation	41.58 ± 13.5	42.28 ± 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
<b>Race</b>			
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
<b>Ethnicity</b>			
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
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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
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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)
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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  $\geq 100$  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
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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 ( $\pm$ 0.03)	7.61 ( $\pm$ 0.04)		

### Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Comparison groups	LY2605541 + Insulin Lispro v Insulin Glargine + Insulin Lispro
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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)
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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  $\geq 100$  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
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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 ( $\pm$ 0.03)	7.42 ( $\pm$ 0.03)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Total hypoglycemia events

End point title	Total hypoglycemia events
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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  $\leq 70$  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
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End point timeframe:

Baseline through 26 weeks, Baseline through 52 weeks

<b>End point values</b>	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: 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  $\geq 100$  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

<b>End point values</b>	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

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

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End point title	Percentage of participants with HbA1c equal to or less than 6.5% and less than 7.0%
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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.

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End point type	Secondary
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End point timeframe:

up to 26 weeks, up to 52 weeks

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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		

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Percentage of participants with total hypoglycemic events**

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End point title	Percentage of participants with total hypoglycemic events
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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.

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End point type	Secondary
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End point timeframe:

Baseline through 26 weeks, Baseline through 52 weeks

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<b>End point values</b>	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: Change in body weight

End point title	Change in body weight
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End point description:

LS means were calculated using MMRM adjusting for treatment, stratification factors (baseline HbA1c [ $\leq 8.5\%$  and  $> 8.5\%$ ], country, baseline LDL-C [ $< 100$  mg/dL (2.6 mmol/L) and  $\geq 100$  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
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End point timeframe:

Baseline, 26 weeks, 52 weeks

<b>End point values</b>	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 ( $\pm 0.14$ )	0.78 ( $\pm 0.16$ )		
Week 52	-0.61 ( $\pm 0.17$ )	1.21 ( $\pm 0.2$ )		

## 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
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End point description:

Hypoglycemic episodes are defined as events associated with the reported signs and symptoms of hypoglycemia and/or a BG concentration of  $\leq 70$  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: Nocturnal Hypoglycemia Rates

End point title	Nocturnal Hypoglycemia Rates
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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  $\leq 70$  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	

<b>End point values</b>	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 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
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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  $\leq 70$  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
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End point timeframe:

up to 26 weeks, up to 52 weeks

<b>End point values</b>	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: 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 [ $\leq 8.5\%$ and $> 8.5\%$ ], country, baseline LDL-C [ $< 100$ mg/dL (2.6 mmol/L) and $\geq 100$ 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 ( $\pm$ 2.75)	155.23 ( $\pm$ 3.25)		
Week 52	142.02 ( $\pm$ 2.95)	171.67 ( $\pm$ 3.48)		

## 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 [ $\leq 8.5\%$ and $> 8.5\%$ ], country, baseline LDL-C [ $< 100$ mg/dL (2.6 mmol/L) and $\geq 100$ 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	

<b>End point values</b>	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: 0300 hours blood glucose (BG) to fasting BG excursion

End point title	0300 hours blood glucose (BG) to fasting BG excursion
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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 [ $\leq 8.5\%$  and  $> 8.5\%$ ], country, baseline LDL-C [ $< 100$  mg/dL (2.6 mmol/L) and  $\geq 100$  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 ( $\pm$ 3.96)	-16.44 ( $\pm$ 4.72)		
Week 52	-23.36 ( $\pm$ 4.1)	-29.01 ( $\pm$ 4.87)		

### 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)
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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 [ $\leq$ 8.5% and  $>$ 8.5%], country, baseline LDL-C [ $<$ 100 mg/dL (2.6 mmol/L) and  $\geq$ 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 ( $\pm$ 1.22)	64.73 ( $\pm$ 1.44)		
Week 52	53.97 ( $\pm$ 1.24)	63.11 ( $\pm$ 1.46)		

## 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)
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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 [ $\leq 8.5\%$  and  $> 8.5\%$ ], country, baseline LDL-C [ $< 100$  mg/dL (2.6 mmol/L) and  $\geq 100$  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
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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 ( $\pm$ 1.96)	151.46 ( $\pm$ 2.31)		
Week 52	159.85 ( $\pm$ 2.02)	153.09 ( $\pm$ 2.39)		

## 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
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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 [ $\leq 8.5\%$  and  $> 8.5\%$ ],

country, LDL-C [ $<100$  mg/dL (2.6 mmol/L) and  $\geq 100$  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 ( $\pm$ 1.09)	179.3 ( $\pm$ 1.29)		
Cholesterol, Week 52	184.66 ( $\pm$ 1.13)	178.13 ( $\pm$ 1.34)		
HDL-C, Week 26	58.44 ( $\pm$ 0.39)	61.52 ( $\pm$ 0.46)		
HDL-C, Week 52	58.13 ( $\pm$ 0.39)	59.52 ( $\pm$ 0.46)		
LDL-C, Week 26	106.25 ( $\pm$ 0.9)	100.9 ( $\pm$ 1.07)		
LDL-C, Week 52	105.8 ( $\pm$ 0.96)	101.2 ( $\pm$ 1.14)		
Triglycerides, Week 26	105.26 ( $\pm$ 2.3)	85.11 ( $\pm$ 2.73)		
Triglycerides, Week 52	104.84 ( $\pm$ 2.17)	88.12 ( $\pm$ 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
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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	

<b>End point values</b>	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: Adult Low Blood Sugar Survey

End point title	Adult Low Blood Sugar Survey
End point description:	
<p>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 (<math>\leq 8.5\%</math> and <math>&gt; 8.5\%</math>), 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.</p>	
<p>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.</p>	
End point type	Secondary
End point timeframe:	
26 weeks and 52 weeks	

<b>End point values</b>	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 ( $\pm 0.55$ )	29.12 ( $\pm 0.65$ )		
Week 52	30.43 ( $\pm 0.59$ )	29.27 ( $\pm 0.7$ )		

## 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
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**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 [ $\leq 8.5\%$  and  $> 8.5\%$ ], country, baseline LDL-C [ $< 100$  mg/dL (2.6 mmol/L) and  $\geq 100$  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 ( $\pm 0.01$ )	0.35 ( $\pm 0.01$ )		
Basal insulin, Week 52 (n=508, 367)	0.47 ( $\pm 0.01$ )	0.35 ( $\pm 0.01$ )		
Meal time insulin, Week 26 (n=542, 388)	0.32 ( $\pm 0.01$ )	0.44 ( $\pm 0.01$ )		
Meal time insulin, Week 52 (n=490, 352)	0.33 ( $\pm 0.01$ )	0.43 ( $\pm 0.01$ )		
Total insulin, Week 26 (n=551, 392)	0.75 ( $\pm 0.01$ )	0.77 ( $\pm 0.01$ )		
Total insulin, Week 52 (n=509, 369)	0.78 ( $\pm 0.01$ )	0.77 ( $\pm 0.02$ )		

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Insulin Treatment Satisfaction Questionnaire**

End point title	Insulin Treatment Satisfaction Questionnaire
End point description:	<p>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 (<math>\leq 8.5\%</math> and <math>&gt; 8.5\%</math>), country, and baseline prior basal insulin therapy (insulin glargine/detemir/other) as fixed effects and baseline ITSQ scores as a covariate.</p> <p>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.</p>
End point type	Secondary
End point timeframe:	up to 52 weeks

<b>End point values</b>	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 ( $\pm$ 0.57)	72.92 ( $\pm$ 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)
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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 ( $\leq$ 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
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End point timeframe:

up to 52 weeks

<b>End point values</b>	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 ( $\pm$ 0)	0.92 ( $\pm$ 0.01)		

### 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)
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**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.

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End point type	Secondary
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End point timeframe:

52 weeks

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<b>End point values</b>	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		

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**Statistical analyses**

No statistical analyses for this end point

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## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Analysis Period 2 (AP2)

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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### Reporting groups

Reporting group title	Glargine + Insulin Lispro
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Reporting group description: -

Reporting group title	LY2605541 + Insulin Lispro
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Reporting group description: -

<b>Serious adverse events</b>	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	
<b>Vascular disorders</b>			
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	
<b>Pregnancy, puerperium and perinatal conditions</b>			
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	
<b>General disorders and administration site conditions</b>			
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	
<b>Immune system disorders</b>			
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	
<b>Investigations</b>			
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	
<b>Injury, poisoning and procedural complications</b>			
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 %

<b>Non-serious adverse events</b>	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 occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
skin papilloma alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
squamous cell carcinoma of skin alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
<b>Vascular disorders</b>			
aortic stenosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
arterial occlusive disease alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
arteriosclerosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
flushing alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
haematoma alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
hypertension alternative dictionary used: MedDRA 16.0			

subjects affected / exposed occurrences (all)	11 / 449 (2.45%) 11	11 / 663 (1.66%) 12	
intra-abdominal haematoma alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
orthostatic hypotension alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
peripheral arterial occlusive disease alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	2 / 663 (0.30%) 2	
phlebitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
spider vein alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
Surgical and medical procedures acrochordon excision alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
artificial crown procedure alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 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 occurrences (all)	3 / 449 (0.67%) 3	1 / 663 (0.15%) 1	
Pregnancy, puerperium and perinatal conditions pregnancy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 449 (0.45%) 2	1 / 663 (0.15%) 1	
General disorders and administration site conditions application site erythema alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
application site pruritus alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
asthenia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 449 (0.45%) 3	3 / 663 (0.45%) 3	
atrophy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
chest discomfort alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
chest pain alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 449 (0.67%) 3	1 / 663 (0.15%) 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 occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
vessel puncture site pain alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
<b>Immune system disorders</b> allergy to chemicals alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
anaphylactic reaction alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
food allergy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
hypersensitivity alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 2	1 / 663 (0.15%) 1	
seasonal allergy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 449 (0.45%) 2	5 / 663 (0.75%) 5	
<b>Reproductive system and breast disorders</b> breast mass alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	3 / 663 (0.45%) 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 occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
polycystic ovaries alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
prostatitis alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
rectocele alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
scrotal pain alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
vaginal haemorrhage alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
vulval disorder alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
Respiratory, thoracic and mediastinal disorders			
asthma alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 3	1 / 663 (0.15%) 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

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

subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
hypertransaminasaemia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
<b>Investigations</b>			
alanine aminotransferase increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 449 (0.67%) 4	17 / 663 (2.56%) 17	
aspartate aminotransferase increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 449 (0.67%) 4	7 / 663 (1.06%) 7	
biopsy skin alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
blood alkaline phosphatase increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	4 / 663 (0.60%) 4	
blood bilirubin increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	4 / 449 (0.89%) 6	0 / 663 (0.00%) 0	
blood cholesterol increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 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 occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
white blood cells urine positive alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
Injury, poisoning and procedural complications			
animal bite alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	3 / 663 (0.45%) 3	
ankle fracture alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 449 (0.45%) 3	1 / 663 (0.15%) 1	
arthropod bite alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 449 (0.67%) 3	1 / 663 (0.15%) 1	
arthropod sting alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	2 / 663 (0.30%) 2	
back injury alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
cartilage injury alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 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 occurrences (all)	2 / 449 (0.45%) 2	4 / 663 (0.60%) 4	
Congenital, familial and genetic disorders phimosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
Cardiac disorders angina pectoris alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	3 / 663 (0.45%) 3	
aortic valve incompetence alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
atrial fibrillation alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
atrial flutter alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
bundle branch block left alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
cardiac failure congestive alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 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
hypoesthesia		
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 occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
sciatica alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 449 (0.45%) 2	1 / 663 (0.15%) 1	
sinus headache alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
syncope alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 2	
tension headache alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	2 / 663 (0.30%) 2	
tremor alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
viith nerve paralysis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 449 (0.67%) 4	2 / 663 (0.30%) 2	
anaemia of chronic disease alternative dictionary used: MedDRA 16.0			

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

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

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

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

subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	1 / 663 (0.15%) 1	
renal failure acute alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 449 (0.45%) 2	0 / 663 (0.00%) 0	
renal failure chronic alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
renal impairment alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
urinary incontinence alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
urinary retention alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
Endocrine disorders hyperparathyroidism alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
hypogonadism alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 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 occurrences (all)	1 / 449 (0.22%) 1	2 / 663 (0.30%) 3	
<b>Infections and infestations</b>			
abscess sweat gland alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
acute sinusitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 449 (0.67%) 3	4 / 663 (0.60%) 4	
acute tonsillitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	1 / 663 (0.15%) 1	
atypical pneumonia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 0	
bacterial infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 2	0 / 663 (0.00%) 0	
body tinea alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 449 (0.00%) 0	3 / 663 (0.45%) 3	
borrelia infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 449 (0.22%) 1	0 / 663 (0.00%) 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
fungus 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

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

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

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported