



Clinical trial results:

Effect of liraglutide on body weight in non-diabetic obese subjects or overweight subjects with comorbidities:

A randomised, double-blind, placebo controlled, parallel group, multi-centre, multinational trial with stratification of subject to either 56 or 160 weeks of treatment based on pre-diabetes status at randomisation.

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

EudraCT number	2008-001049-24
Trial protocol	IE FI ES DE DK AT GB FR IT NL BE PL
Global end of trial date	02 March 2015

Results information

Result version number	v1 (current)
This version publication date	27 May 2016
First version publication date	27 May 2016

Trial information

Trial identification

Sponsor protocol code	NN8022-1839
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01272219
WHO universal trial number (UTN)	U1111-1118-7871

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 January 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 March 2013
Global end of trial reached?	Yes
Global end of trial date	02 March 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To establish the efficacy of 3.0 mg liraglutide compared to liraglutide placebo in inducing and maintaining weight loss over 56 weeks in obese subjects and overweight subjects with comorbidities.

To investigate the long term efficacy of 3.0 mg liraglutide versus liraglutide placebo in delaying the onset of type 2 diabetes in obese subjects and overweight subjects with co-morbidities diagnosed with pre-diabetes.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (59th WMA General Assembly, Seoul, 01-Oct-2008) and ICH Good Clinical Practice (01-May-1996) and 21 CFR 312.120.

Background therapy:

Not applicable.

Evidence for comparator:

Not applicable.

Actual start date of recruitment	01 June 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 65
Country: Number of subjects enrolled	Brazil: 143
Country: Number of subjects enrolled	Canada: 188
Country: Number of subjects enrolled	Hong Kong: 30
Country: Number of subjects enrolled	India: 86
Country: Number of subjects enrolled	Israel: 82
Country: Number of subjects enrolled	Mexico: 90
Country: Number of subjects enrolled	Russian Federation: 160
Country: Number of subjects enrolled	Serbia: 21
Country: Number of subjects enrolled	South Africa: 31
Country: Number of subjects enrolled	Switzerland: 65
Country: Number of subjects enrolled	Turkey: 18
Country: Number of subjects enrolled	United States: 1639

Country: Number of subjects enrolled	Netherlands: 163
Country: Number of subjects enrolled	Norway: 47
Country: Number of subjects enrolled	Poland: 70
Country: Number of subjects enrolled	Spain: 95
Country: Number of subjects enrolled	United Kingdom: 183
Country: Number of subjects enrolled	Austria: 70
Country: Number of subjects enrolled	Belgium: 48
Country: Number of subjects enrolled	Denmark: 70
Country: Number of subjects enrolled	Finland: 67
Country: Number of subjects enrolled	France: 57
Country: Number of subjects enrolled	Germany: 121
Country: Number of subjects enrolled	Hungary: 30
Country: Number of subjects enrolled	Ireland: 10
Country: Number of subjects enrolled	Italy: 82
Worldwide total number of subjects	3731
EEA total number of subjects	1113

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	3526
From 65 to 84 years	205
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 191 sites in 27 countries: Australia:4, Austria:3, Belgium:2, Brazil:5, Canada:11, Denmark:3, Finland:3, France:5, Germany:8, Hong Kong:1, Hungary:2, India:8, Ireland:1, Israel:7, Italy:7, Mexico:4, Netherlands:5, Norway:3, Poland:5, Russia:7, Serbia:2, South Africa:3, Spain:6, Switzerland:5, Turkey:4, UK:8 and US:69.

Pre-assignment

Screening details:

Included subjects were without type 2 diabetes, male or female, age 18 years or above, obese (body mass index [BMI] ≥ 30.0 kg/m²) or overweight (BMI ≥ 27.0 kg/m²) with treated or untreated comorbid dyslipidaemia and/or hypertension, stable body weight (< 5 kg self-reported change during the previous 3 months), preceding failed dietary effort.

Period 1

Period 1 title	Main Period: Week 0 to Week 56
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Treatment allocation was blinded to all subjects, investigator and Novo Nordisk. After data base lock of the 70-week data (56-week; main treatment period + 12-week; re-randomised treatment period + 2-week; follow-up), Novo Nordisk was un-blinded. However subjects and investigator remained blinded to the treatment allocation for the remainder of the trial (treatment period up to 160-week as well as the 12-week off-drug follow-up period).

Arms

Are arms mutually exclusive?	Yes
Arm title	Liraglutide 3.0 mg, no Pre-diabetes

Arm description:

Subjects with no pre-diabetes at screening received liraglutide 3.0 mg for a duration of 56-week.

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

Dosage and administration details:

Liraglutide 3.0 mg was administered once daily (OD) by subcutaneous (s.c.; under the skin) injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Arm title	Liraglutide Placebo, no Pre-diabetes
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Arm description:

Subjects with no pre-diabetes at screening received liraglutide placebo for a duration of 56-week.

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

Dosage and administration details:

Liraglutide placebo was administered OD by s.c. injections with the FlexPen® either in the abdomen,

thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Arm title	Liraglutide 3.0 mg, Pre-diabetes
Arm description: Subjects with pre-diabetes at screening received liraglutide 3.0 mg for a duration of 56-week.	
Arm type	Experimental
Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	Saxenda®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide 3.0 mg was administered OD by s.c. injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Arm title	Liraglutide Placebo, Pre-diabetes
Arm description: Subjects with pre-diabetes at screening received liraglutide placebo for a duration of 56-weeks.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide placebo was administered OD by s.c. injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Number of subjects in period 1	Liraglutide 3.0 mg, no Pre-diabetes	Liraglutide Placebo, no Pre-diabetes	Liraglutide 3.0 mg, Pre-diabetes
Started	959	487	1528
Exposed	957	487	1524
Completed	679	296	1110
Not completed	280	191	418
Adverse event, serious fatal	1	1	-
Adverse event, non-fatal	85	15	152
Withdrawal criteria	122	114	172
Unclassified	36	29	42
Lack of efficacy	11	14	12
Protocol deviation	25	18	40

Number of subjects in period 1	Liraglutide Placebo, Pre-diabetes
Started	757

Exposed	755
Completed	505
Not completed	252
Adverse event, serious fatal	1
Adverse event, non-fatal	28
Withdrawal criteria	147
Unclassified	34
Lack of efficacy	22
Protocol deviation	20

Period 2

Period 2 title	Main + Extension Period: Week 0-172
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Treatment allocation was blinded to all subjects, investigator and Novo Nordisk. After data base lock of the 70-week data (56-week; main treatment period + 12-week; re-randomised treatment period + 2-week; follow-up), Novo Nordisk was un-blinded. However subjects and investigator remained blinded to the treatment allocation for the remainder of the trial (treatment period up to 160-week as well as the 12-week off-drug follow-up period).

Arms

Are arms mutually exclusive?	Yes
Arm title	Liraglutide 3.0 mg, Pre-diabetes (Week 0-160)

Arm description:

Subjects with pre-diabetes at screening were stratified to 160-week of treatment with liraglutide 3.0 mg followed by an off-drug observation follow-up period of 12-week. The total duration of this treatment arm from randomisation to follow-up was 172-week. Due to incorrect stratification, some subjects without pre-diabetes erroneously entered this arm.

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

Dosage and administration details:

Liraglutide 3.0 mg was administered OD by s.c. injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Arm title	Liraglutide Placebo, Pre-diabetes (Week 0-160)
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Arm description:

Subjects with pre-diabetes at screening were stratified to 160-week of treatment with liraglutide placebo followed by an off-drug observation follow-up period of 12-week. The total duration of this treatment arm from randomisation to follow-up was 172-week. Due to incorrect stratification, some subjects without pre-diabetes erroneously entered this arm.

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

Dosage and administration details:

Liraglutide placebo was administered OD by s.c. injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Number of subjects in period 2^[1]	Liraglutide 3.0 mg, Pre-diabetes (Week 0-160)	Liraglutide Placebo, Pre-diabetes (Week 0-160)
Started	1505	749
Exposed	1501	747
Completed	783	327
Not completed	722	422
Adverse event, serious fatal	2	2
Adverse event, non-fatal	189	41
Withdrawal criteria	364	256
Unclassified	61	51
Protocol deviation	76	36
Lack of efficacy	29	36
Missing reason	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The main period (week 0-56) presents data for all subjects (i.e., subjects with pre-diabetes and subjects with no pre-diabetes at baseline), who initiated the study and who received treatment (either liraglutide 3.0mg or liraglutide placebo) for a duration of 56-week. This period (week 0-172) presents data only for subjects with pre-diabetes status at baseline and who received either liraglutide 3.0mg or liraglutide placebo in the main + extension period (i.e., week 0-160).

Period 3

Period 3 title	Re-randomised Period: Week 56 to Week 68
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Treatment allocation was blinded to all subjects, investigator and Novo Nordisk. After data base lock of the 70-week data (56-week; main treatment period + 12-week; re-randomised treatment period + 2-week; follow-up), Novo Nordisk was un-blinded. However subjects and investigator remained blinded to the treatment allocation for the remainder of the trial (treatment period up to 160-week as well as the 12-week off-drug follow-up period).

Arms

Are arms mutually exclusive?	Yes
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Arm title	Liraglutide 3.0mg (week 0-56)/Liraglutide 3.0mg (week 56-68)
Arm description: Subjects in main period (with no pre-diabetes at screening) receiving liraglutide 3.0 mg for 56-week were re-randomised (1:1 into liraglutide 3.0 mg or liraglutide placebo) to continue treatment with liraglutide 3.0 mg for the next 12-week (weeks 56-68), followed by a 2-week off-drug follow-up period. Due to incorrect stratification of subjects, some pre-diabetic subjects erroneously entered this arm.	
Arm type	Experimental
Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	Saxenda®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide 3.0 mg was administered OD by s.c. injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Arm title	Liraglutide 3.0mg (week 0-56)/Liraglutide Placebo (week 56-68)
Arm description: Subjects in main period (with no pre-diabetes at screening) receiving liraglutide 3.0 mg for 56-week were re-randomised (1:1 into liraglutide 3.0 mg or liraglutide placebo) to continue treatment with liraglutide placebo for the next 12-week (weeks 56-68), followed by a 2-week off-drug follow-up period. Due to incorrect stratification of subjects, some pre-diabetic subjects erroneously entered this arm.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide placebo was administered OD by s.c. injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Arm title	Liraglutide Placebo(week 0-56)/Liraglutide Placebo(week 56-68)
Arm description: Subjects in main period (with no pre-diabetes at screening) received liraglutide placebo for 56-week and then continued with liraglutide placebo for additional 12-week (weeks 56-68), followed by a 2-week off-drug follow-up period. Due to incorrect stratification of subjects, some pre-diabetic subjects erroneously entered this arm.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide placebo was administered OD by s.c. injections with the FlexPen® either in the abdomen, thigh or upper arm. Injections could be done at any time of day irrespective of meals.

Number of subjects in period 3^[2]	Liraglutide 3.0mg (week 0-56)/Liraglutide 3.0mg (week 56-68)	Liraglutide 3.0mg (week 0-56)/Liraglutide Placebo (week 56-	Liraglutide Placebo(week 0-56)/Liraglutide Placebo(week 56-
Started	351	350	304
Completed	342	343	289
Not completed	9	7	15
Adverse event, non-fatal	1	1	2
Withdrawal criteria	6	4	7
Unclassified	1	2	2
Protocol deviation	1	-	3
Lack of efficacy	-	-	1

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The "main + extension period (week 0-172)" presents data for subjects with pre-diabetes status at baseline and who received either liraglutide 3.0mg or liraglutide placebo in the main + extension period (i.e., week 0-160). This period presents data only for subjects with no pre-diabetes status at baseline, completed treatment in the main period (week 0-56) and who received treatment in the re-randomisation period (week 56-68).

Baseline characteristics

Reporting groups

Reporting group title	Liraglutide 3.0 mg, no Pre-diabetes
Reporting group description:	
Subjects with no pre-diabetes at screening received liraglutide 3.0 mg for a duration of 56-week.	
Reporting group title	Liraglutide Placebo, no Pre-diabetes
Reporting group description:	
Subjects with no pre-diabetes at screening received liraglutide placebo for a duration of 56-week.	
Reporting group title	Liraglutide 3.0 mg, Pre-diabetes
Reporting group description:	
Subjects with pre-diabetes at screening received liraglutide 3.0 mg for a duration of 56-week.	
Reporting group title	Liraglutide Placebo, Pre-diabetes
Reporting group description:	
Subjects with pre-diabetes at screening received liraglutide placebo for a duration of 56-weeks.	

Reporting group values	Liraglutide 3.0 mg, no Pre-diabetes	Liraglutide Placebo, no Pre-diabetes	Liraglutide 3.0 mg, Pre-diabetes
Number of subjects	959	487	1528
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	41.6	41.5	47.4
standard deviation	± 11.7	± 11.5	± 11.8
Gender categorical			
Units: Subjects			
Female	801	390	1156
Male	158	97	372
Fasting Body Weight			
Units: Kg			
arithmetic mean	104	103.6	107.6
standard deviation	± 20.1	± 21.2	± 21.8
Body Mass Index (BMI)			
Units: kg/m ²			
arithmetic mean	37.5	37.4	38.8
standard deviation	± 6.2	± 6.2	± 6.4
Glycosylated Haemoglobin (HbA1c)			
Units: Percentage			
arithmetic mean	5.3	5.3	5.8
standard deviation	± 0.3	± 0.3	± 0.3
Fasting Plasma Glucose (FPG)			
Units: mmol/L			
arithmetic mean	5	5.1	5.5
standard deviation	± 0.4	± 0.5	± 0.6

Reporting group values	Liraglutide Placebo, Pre-diabetes	Total	
Number of subjects	757	3731	

Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	47.2 ± 11.8	-	
Gender categorical Units: Subjects			
Female	581	2928	
Male	176	803	
Fasting Body Weight Units: Kg arithmetic mean standard deviation	107.9 ± 21.8	-	
Body Mass Index (BMI) Units: kg/m ² arithmetic mean standard deviation	39 ± 6.3	-	
Glycosylated Haemoglobin (HbA1c) Units: Percentage arithmetic mean standard deviation	5.7 ± 0.3	-	
Fasting Plasma Glucose (FPG) Units: mmol/L arithmetic mean standard deviation	5.5 ± 0.5	-	

End points

End points reporting groups

Reporting group title	Liraglutide 3.0 mg, no Pre-diabetes
Reporting group description: Subjects with no pre-diabetes at screening received liraglutide 3.0 mg for a duration of 56-week.	
Reporting group title	Liraglutide Placebo, no Pre-diabetes
Reporting group description: Subjects with no pre-diabetes at screening received liraglutide placebo for a duration of 56-week.	
Reporting group title	Liraglutide 3.0 mg, Pre-diabetes
Reporting group description: Subjects with pre-diabetes at screening received liraglutide 3.0 mg for a duration of 56-week.	
Reporting group title	Liraglutide Placebo, Pre-diabetes
Reporting group description: Subjects with pre-diabetes at screening received liraglutide placebo for a duration of 56-weeks.	
Reporting group title	Liraglutide 3.0 mg, Pre-diabetes (Week 0-160)
Reporting group description: Subjects with pre-diabetes at screening were stratified to 160-week of treatment with liraglutide 3.0 mg followed by an off-drug observation follow-up period of 12-week. The total duration of this treatment arm from randomisation to follow-up was 172-week. Due to incorrect stratification, some subjects without pre-diabetes erroneously entered this arm.	
Reporting group title	Liraglutide Placebo, Pre-diabetes (Week 0-160)
Reporting group description: Subjects with pre-diabetes at screening were stratified to 160-week of treatment with liraglutide placebo followed by an off-drug observation follow-up period of 12-week. The total duration of this treatment arm from randomisation to follow-up was 172-week. Due to incorrect stratification, some subjects without pre-diabetes erroneously entered this arm.	
Reporting group title	Liraglutide 3.0mg (week 0-56)/Liraglutide 3.0mg (week 56-68)
Reporting group description: Subjects in main period (with no pre-diabetes at screening) receiving liraglutide 3.0 mg for 56-week were re-randomised (1:1 into liraglutide 3.0 mg or liraglutide placebo) to continue treatment with liraglutide 3.0 mg for the next 12-week (weeks 56-68), followed by a 2-week off-drug follow-up period. Due to incorrect stratification of subjects, some pre-diabetic subjects erroneously entered this arm.	
Reporting group title	Liraglutide 3.0mg (week 0-56)/Liraglutide Placebo (week 56-68)
Reporting group description: Subjects in main period (with no pre-diabetes at screening) receiving liraglutide 3.0 mg for 56-week were re-randomised (1:1 into liraglutide 3.0 mg or liraglutide placebo) to continue treatment with liraglutide placebo for the next 12-week (weeks 56-68), followed by a 2-week off-drug follow-up period. Due to incorrect stratification of subjects, some pre-diabetic subjects erroneously entered this arm.	
Reporting group title	Liraglutide Placebo(week 0-56)/Liraglutide Placebo(week 56-68)
Reporting group description: Subjects in main period (with no pre-diabetes at screening) received liraglutide placebo for 56-week and then continued with liraglutide placebo for additional 12-week (weeks 56-68), followed by a 2-week off-drug follow-up period. Due to incorrect stratification of subjects, some pre-diabetic subjects erroneously entered this arm.	
Subject analysis set title	Liraglutide 3.0 mg (56-Week)
Subject analysis set type	Full analysis
Subject analysis set description: Subjects with pre-diabetes and subjects with no pre-diabetes at baseline, received liraglutide 3.0 mg, OD by s.c. injection for a duration of 56-week, from randomisation.	
Subject analysis set title	Liraglutide Placebo (56-Week)
Subject analysis set type	Full analysis
Subject analysis set description: Subjects with pre-diabetes and subjects with no pre-diabetes at baseline, received liraglutide placebo,	

OD by s.c. injection for a duration of 56-week, from randomisation.

Subject analysis set title	Liraglutide 3.0 mg (160-Week)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with pre-diabetes at baseline, received liraglutide 3.0 mg, OD by s.c. injection for a duration of 160-week, from randomisation. Due to incorrect stratification, some subjects without pre-diabetes erroneously entered this arm.

Subject analysis set title	Liraglutide Placebo (160-Week)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with pre-diabetes at baseline, received liraglutide placebo, OD by s.c. injection for a duration of 160-week, from randomisation. Due to incorrect stratification, some subjects without pre-diabetes erroneously entered this arm.

Primary: Change from baseline in body weight (fasting) at 56 weeks

End point title	Change from baseline in body weight (fasting) at 56 weeks
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End point description:

The observed mean change from baseline in fasting body weight (%) after 56-weeks of treatment (main treatment period). Analysis population: the full analysis set (FAS) included all randomised subjects who were exposed to at least one dose of trial product (liraglutide 3.0 mg or liraglutide placebo) and who provided at least one post-baseline efficacy value. Missing data were imputed using last observation carried forward (LOCF).

End point type	Primary
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End point timeframe:

Week 0, Week 56

End point values	Liraglutide 3.0 mg (56-Week)	Liraglutide Placebo (56-Week)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2432 ^[1]	1220 ^[2]		
Units: Percent change				
arithmetic mean (standard deviation)	-7.98 (± 6.67)	-2.62 (± 5.74)		

Notes:

[1] - Number of subjects in FAS = 2437. Number of subjects contributing to analysis = 2432.

[2] - Number of subjects in FAS = 1225. Number of subjects contributing to analysis = 1220.

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Analysis of covariance (ANCOVA) model with treatment, country, sex, pre-diabetes status at screening, baseline BMI stratum and an interaction between pre-diabetes status at screening and BMI stratum as fixed factors, and the baseline value as covariate.

Comparison groups	Liraglutide 3.0 mg (56-Week) v Liraglutide Placebo (56-Week)
Number of subjects included in analysis	3652
Analysis specification	Pre-specified
Analysis type	superiority ^[3]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Estimated mean difference
Point estimate	-5.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.82
upper limit	-4.95

Notes:

[3] - Null-hypothesis: no treatment difference between treatment arms, i.e. liraglutide 3.0 mg and liraglutide placebo. Liraglutide 3.0 mg was considered superior to placebo in inducing and maintaining weight loss, if the estimated treatment effect (liraglutide 3.0 mg - liraglutide placebo) was statistically significantly smaller than zero.

Primary: Proportion of subjects losing at least 5% of baseline body weight at 56 weeks

End point title	Proportion of subjects losing at least 5% of baseline body weight at 56 weeks
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End point description:

Percentage of subjects losing at least 5% of baseline fasting body weight after 56-weeks of treatment (main treatment period). Analysis population: the FAS included all randomised subjects who were exposed to at least one dose of trial product (liraglutide 3.0 mg or liraglutide placebo) and who provided at least one post-baseline efficacy value. Missing data were imputed using LOCF.

End point type	Primary
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End point timeframe:

At Week 56

End point values	Liraglutide 3.0 mg (56-Week)	Liraglutide Placebo (56-Week)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2432 ^[4]	1220 ^[5]		
Units: Percentage of subjects				
number (not applicable)	63.2	27.1		

Notes:

[4] - Number of subjects in FAS = 2437. Number of subjects contributing to analysis = 2432.

[5] - Number of subjects in FAS = 1225. Number of subjects contributing to analysis = 1220.

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

The model included treatment, country, sex, pre-diabetes status at screening, BMI stratum and an interaction between pre-diabetes status at screening and BMI stratum as fixed factors, and the baseline value as covariate.

Comparison groups	Liraglutide 3.0 mg (56-Week) v Liraglutide Placebo (56-Week)
Number of subjects included in analysis	3652
Analysis specification	Pre-specified
Analysis type	superiority ^[6]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.12
upper limit	5.6

Notes:

[6] - Null-hypothesis: no treatment difference between treatment arms, i.e. liraglutide 3.0 mg and liraglutide placebo. Liraglutide 3.0 mg was considered superior to placebo in inducing and maintaining weight loss as assessed by the proportion of subjects losing $\geq 5\%$ of their fasting baseline weight, if the estimated odds ratio (liraglutide 3.0 mg/liraglutide placebo) was statistically significantly greater than one.

Primary: Proportion of subjects losing more than 10% of baseline body weight at 56 weeks

End point title	Proportion of subjects losing more than 10% of baseline body weight at 56 weeks
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End point description:

Percentage of subjects losing $>10\%$ of baseline fasting body weight after 56-weeks of treatment (main treatment period). Analysis population: the FAS included all randomised subjects who were exposed to at least one dose of trial product (liraglutide 3.0 mg or liraglutide placebo) and who provided at least one post-baseline efficacy value. Missing data were imputed using LOCF.

End point type	Primary
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End point timeframe:

At Week 56

End point values	Liraglutide 3.0 mg (56-Week)	Liraglutide Placebo (56-Week)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2432 ^[7]	1220 ^[8]		
Units: Percentage of subjects				
number (not applicable)	33.1	10.6		

Notes:

[7] - Number of subjects in FAS = 2437. Number of subjects contributing to analysis = 2432.

[8] - Number of subjects in FAS = 1225. Number of subjects contributing to analysis = 1220.

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

The model included treatment, country, sex, pre-diabetes status at screening, BMI stratum and an interaction between pre-diabetes status at screening and BMI stratum as fixed factors, and the baseline value as covariate.

Comparison groups	Liraglutide 3.0 mg (56-Week) v Liraglutide Placebo (56-Week)
Number of subjects included in analysis	3652
Analysis specification	Pre-specified
Analysis type	superiority ^[9]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.34

Confidence interval	
level	95 %
sides	2-sided
lower limit	3.54
upper limit	5.32

Notes:

[9] - Null-hypothesis: no treatment difference between treatment arms, i.e. liraglutide 3.0 mg and liraglutide placebo. Liraglutide 3.0 mg was considered superior to placebo in inducing and maintaining weight loss as assessed by the proportion of subjects losing >10% of their fasting baseline weight, if the estimated odds ratio (liraglutide 3.0 mg/liraglutide placebo) was statistically significantly greater than one.

Primary: Proportion of subjects with onset of type 2 diabetes at 160 weeks (among subjects with prediabetes at baseline)

End point title	Proportion of subjects with onset of type 2 diabetes at 160 weeks (among subjects with prediabetes at baseline)
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End point description:

Proportion of subjects with onset of Type 2 diabetes mellitus (T2DM) at week 160 (main + extension treatment period) among subjects with pre-diabetes at baseline - evaluated as time to onset of T2DM. Subjects included in FAS, who were stratified to 160-week of treatment (i.e., excluding 37 subjects with pre-diabetes who entered the re-randomised period and including 6 subjects without pre-diabetes incorrectly stratified to the 160-week treatment period). Analysis population: Subjects included in the FAS, who were stratified to 160-week of treatment; all randomised subjects who were exposed to at least one dose of trial product (liraglutide 3.0 mg or liraglutide placebo) and with at least one post-baseline efficacy measurement, who were stratified to 160-week of treatment. Missing data were imputed using LOCF.

End point type	Primary
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End point timeframe:

At 160-week

End point values	Liraglutide 3.0 mg (160-Week)	Liraglutide Placebo (160-Week)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1472 ^[10]	738 ^[11]		
Units: Number of subjects	26	46		

Notes:

[10] - Both the number of subjects in FAS and number of subjects contributing to analysis = 1472.

[11] - Both the number of subjects in FAS and number of subjects contributing to analysis = 738.

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Weibull model was used; included treatment, sex and BMI stratification factor as fixed factors and baseline FPG as a covariate. The treatment estimate was the factor that the time to event is multiplied with for liraglutide 3.0 mg compared to placebo.

Comparison groups	Liraglutide 3.0 mg (160-Week) v Liraglutide Placebo (160-Week)
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Number of subjects included in analysis	2210
Analysis specification	Pre-specified
Analysis type	superiority ^[12]
P-value	< 0.0001
Method	Weibull analysis
Parameter estimate	Treatment estimate
Point estimate	2.681
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.856
upper limit	3.872

Notes:

[12] - If the estimated time-to-event ratio (liraglutide 3.0 mg/ placebo), as assessed by the survival endpoint describing the time until onset of type 2 diabetes mellitus (T2DM) ('diabetes-free time'), is statistically significantly >1, then liraglutide 3.0 mg was to be considered superior to placebo in delaying the onset of T2DM in subjects with pre-diabetes at baseline.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

For Arm 1 and Arm 2: week 0 to week 70 (68-week of treatment period + 2-week of follow-up). For Arm 3 and Arm 4: week 0 to week 172 (160-week of treatment period + 12-week of follow-up).

Adverse event reporting additional description:

A total of 37 pre-diabetic subjects erroneously entered the re-randomised period and their adverse events (AEs) were counted under the "pre-diabetic arms". A total of 6 subjects without pre-diabetes incorrectly stratified to the 160-week treatment period and their AEs were counted under the "no pre-diabetes arms".

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	With Pre-Diabetes - Liraglutide 3.0 mg
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Reporting group description:

Subjects with pre-diabetes at screening were stratified to 160-week of treatment with liraglutide 3.0 mg followed by an off-drug observation follow-up period of 12-week. The total duration of this treatment arm from randomisation to follow-up was 172-week.

Reporting group title	With Pre-Diabetes - Liraglutide Placebo
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Reporting group description:

Subjects with pre-diabetes at screening were stratified to 160-week of treatment with liraglutide placebo followed by an off-drug observation follow-up period of 12-week. The total duration of this treatment arm from randomisation to follow-up was 172-week.

Reporting group title	Without Pre-Diabetes - Liraglutide 3.0 mg
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Reporting group description:

Subjects with no pre-diabetes at screening received liraglutide 3.0 mg for 56 weeks followed by a re-randomisation (1:1 into liraglutide 3.0 mg or liraglutide placebo) period of 12 weeks (weeks 56-68) and then an off-drug follow-up period of 2 weeks. The total duration of this treatment arm from randomisation to follow-up was 70 weeks.

Reporting group title	Without Pre-Diabetes - Liraglutide Placebo
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Reporting group description:

Subjects with no pre-diabetes at screening received liraglutide placebo for 56 weeks and then continued with liraglutide placebo for additional 12 weeks (weeks 56-68), followed by a 2 weeks off-drug follow-up period. The total duration of this treatment arm from randomisation to follow-up was 70 weeks.

Serious adverse events	With Pre-Diabetes - Liraglutide 3.0 mg	With Pre-Diabetes - Liraglutide Placebo	Without Pre-Diabetes - Liraglutide 3.0 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	230 / 1524 (15.09%)	96 / 755 (12.72%)	59 / 957 (6.17%)
number of deaths (all causes)	2	2	1
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal adenoma			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign salivary gland neoplasm			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct cancer			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	5 / 1524 (0.33%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer in situ			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage III			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour of the small bowel			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholesteatoma			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage 0			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysplastic naevus			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of breast			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of bone			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic adenoma			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mantle cell lymphoma stage I			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melanocytic naevus			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm skin			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Prostate cancer			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seborrhoeic keratosis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	3 / 1524 (0.20%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal cancer			

subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism venous			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicophlebitis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			

subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abdominoplasty			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion induced			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary arterial stent insertion			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary revascularisation			
subjects affected / exposed	3 / 1524 (0.20%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrectomy			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric bypass			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart transplant			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip arthroplasty			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament operation			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipectomy			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mammoplasty			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity surgery			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele repair			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion missed			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 1524 (0.00%)	2 / 755 (0.26%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device complication			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metaplasia			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	5 / 1524 (0.33%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	2 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer haemorrhage			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Amyloidosis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Miscarriage of partner			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
Adnexa uteri cyst			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical dysplasia			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysmenorrhoea			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial disorder			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial hyperplasia			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menometrorrhagia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	3 / 1524 (0.20%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic adhesions			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymenorrhoea			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			
subjects affected / exposed	3 / 1524 (0.20%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 1524 (0.13%)	1 / 755 (0.13%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			

subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	3 / 1524 (0.20%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	6 / 1524 (0.39%)	0 / 755 (0.00%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	4 / 6	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	9 / 1524 (0.59%)	1 / 755 (0.13%)	4 / 957 (0.42%)
occurrences causally related to treatment / all	6 / 9	1 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	22 / 1524 (1.44%)	6 / 755 (0.79%)	7 / 957 (0.73%)
occurrences causally related to treatment / all	8 / 23	4 / 6	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder polyp			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cyst			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic lesion			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheterisation cardiac			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cartilage injury			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dispensing error			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1524 (0.00%)	4 / 755 (0.53%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			

subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus lesion			
subjects affected / exposed	0 / 1524 (0.00%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post laminectomy syndrome			

subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 1524 (0.00%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric injury			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong drug administered			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple endocrine adenomatosis Type I			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute coronary syndrome			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease mixed			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	4 / 1524 (0.26%)	2 / 755 (0.26%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	2 / 4	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Cardiomegaly			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Congestive cardiomyopathy			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Left ventricular dysfunction			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain stem infarction			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	2 / 1524 (0.13%)	1 / 755 (0.13%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord herniation			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	3 / 1524 (0.20%)	1 / 755 (0.13%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 1524 (0.07%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIth nerve paralysis			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bandaemia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercoagulation			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	3 / 1524 (0.20%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	3 / 1524 (0.20%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Barrett's oesophagus			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Caecitis			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 1524 (0.00%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecal incontinence			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	4 / 1524 (0.26%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal prolapse			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic cyst			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	3 / 1524 (0.20%)	1 / 755 (0.13%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	3 / 3	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia, obstructive			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutis laxa			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panniculitis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Bladder prolapse			
subjects affected / exposed	1 / 1524 (0.07%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	4 / 1524 (0.26%)	1 / 755 (0.13%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	2 / 1524 (0.13%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism primary			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic nodular goitre			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1524 (0.00%)	2 / 755 (0.26%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis			
subjects affected / exposed	1 / 1524 (0.07%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	4 / 1524 (0.26%)	3 / 755 (0.40%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			

subjects affected / exposed	6 / 1524 (0.39%)	1 / 755 (0.13%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint laxity			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	12 / 1524 (0.79%)	5 / 755 (0.66%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal wall infection			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolar osteitis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	4 / 1524 (0.26%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 1524 (0.00%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	3 / 1524 (0.20%)	3 / 755 (0.40%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	3 / 1524 (0.20%)	1 / 755 (0.13%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	3 / 1524 (0.20%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	4 / 1524 (0.26%)	0 / 755 (0.00%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	2 / 4	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	2 / 957 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oophoritis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 1524 (0.13%)	1 / 755 (0.13%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			

subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 1524 (0.07%)	2 / 755 (0.26%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 1524 (0.13%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	3 / 1524 (0.20%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval abscess			
subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Central obesity			

subjects affected / exposed	0 / 1524 (0.00%)	1 / 755 (0.13%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 1524 (0.00%)	0 / 755 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	1 / 1524 (0.07%)	0 / 755 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	1 / 1524 (0.07%)	3 / 755 (0.40%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Without Pre-Diabetes - Liraglutide Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 487 (3.90%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal adenoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign salivary gland neoplasm			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct cancer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	2 / 487 (0.41%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Breast cancer in situ			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer metastatic			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer stage III			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carcinoid tumour of the small bowel			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholesteatoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic myeloid leukaemia			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon adenoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer metastatic			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer stage 0			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysplastic naevus			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fibroadenoma of breast			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemangioma of bone			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic adenoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal cancer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lentigo maligna			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mantle cell lymphoma stage I			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Melanocytic naevus			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm skin			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seborrhoeic keratosis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid cancer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal cancer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Circulatory collapse			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolism venous			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicophlebitis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Abdominoplasty			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion induced			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary arterial stent insertion			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary revascularisation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrectomy			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric bypass			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart transplant			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip arthroplasty			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ligament operation			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipectomy			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mammoplasty			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obesity surgery			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectocele repair			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion missed			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion threatened			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ectopic pregnancy			

subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	2 / 487 (0.41%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cyst			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inflammation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Medical device complication			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metaplasia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			

subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulcer haemorrhage			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Amyloidosis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Miscarriage of partner			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Adnexa uteri cyst			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Cervical dysplasia				
subjects affected / exposed	1 / 487 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dysmenorrhoea				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial disorder				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial hyperplasia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometriosis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Menometrorrhagia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Menorrhagia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metrorrhagia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic adhesions			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polymenorrhoea			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectocele			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine polyp			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine prolapse			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal septum deviation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary fibrosis			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			

subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gallbladder polyp			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cyst			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic lesion			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amylase increased			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Catheterisation cardiac			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipase increased			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight decreased			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight increased			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Animal bite			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cartilage injury			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug dispensing error			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hand fracture			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb traumatic amputation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus lesion			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle injury			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle strain			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post laminectomy syndrome			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural pain			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stab wound			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon injury			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureteric injury			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wrong drug administered			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple endocrine adenomatosis Type I			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Angina unstable				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve disease mixed				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure chronic				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac tamponade				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomegaly			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive heart disease			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular dysfunction			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palpitations			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Brain stem infarction			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery aneurysm			

subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervicobrachial syndrome			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Intercostal neuralgia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial pressure increased			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord herniation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VIIth nerve paralysis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bandaemia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercoagulation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abdominal pain				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	1 / 487 (0.21%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Anal fissure				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal fistula				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Barrett's oesophagus				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Caecitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulum			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Faecal incontinence			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			

subjects affected / exposed	1 / 487 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal perforation				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal prolapse				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic cyst				

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia, obstructive			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cutis laxa			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eczema			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Excessive skin			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Panniculitis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Bladder prolapse			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus ureteric			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
IgA nephropathy			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oliguria			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cyst			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure acute			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal infarct			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress urinary incontinence			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism primary			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxic nodular goitre			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Back pain				
subjects affected / exposed	1 / 487 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical spinal stenosis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chondromalacia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chondropathy				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dupuytren's contracture				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint laxity				

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar spinal stenosis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myalgia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neck pain			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in jaw			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rheumatoid arthritis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovial cyst			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal wall infection			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess neck			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alveolar osteitis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	1 / 487 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis infective			

subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain abscess				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast abscess				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Campylobacter gastroenteritis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus infection				

subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Empyema				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 487 (0.21%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis A				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incision site infection				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lobar pneumonia				

subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oophoritis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				
subjects affected / exposed	0 / 487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulval abscess			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Central obesity			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			

subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypocalcaemia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemia			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obesity			
subjects affected / exposed	0 / 487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	With Pre-Diabetes - Liraglutide 3.0 mg	With Pre-Diabetes - Liraglutide Placebo	Without Pre- Diabetes - Liraglutide 3.0 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1342 / 1524 (88.06%)	586 / 755 (77.62%)	843 / 957 (88.09%)
Investigations			
Lipase increased			
subjects affected / exposed	145 / 1524 (9.51%)	24 / 755 (3.18%)	35 / 957 (3.66%)
occurrences (all)	207	26	41
Vascular disorders			
Hypertension			
subjects affected / exposed	74 / 1524 (4.86%)	48 / 755 (6.36%)	22 / 957 (2.30%)
occurrences (all)	86	58	23
Nervous system disorders			
Dizziness			
subjects affected / exposed	149 / 1524 (9.78%)	55 / 755 (7.28%)	67 / 957 (7.00%)
occurrences (all)	197	73	81
Headache			

subjects affected / exposed	273 / 1524 (17.91%)	124 / 755 (16.42%)	127 / 957 (13.27%)
occurrences (all)	432	223	178
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	154 / 1524 (10.10%)	58 / 755 (7.68%)	79 / 957 (8.25%)
occurrences (all)	190	67	89
Injection site haematoma			
subjects affected / exposed	91 / 1524 (5.97%)	61 / 755 (8.08%)	64 / 957 (6.69%)
occurrences (all)	102	69	68
Oedema peripheral			
subjects affected / exposed	53 / 1524 (3.48%)	47 / 755 (6.23%)	22 / 957 (2.30%)
occurrences (all)	60	58	25
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	112 / 1524 (7.35%)	37 / 755 (4.90%)	62 / 957 (6.48%)
occurrences (all)	150	49	79
Abdominal pain upper			
subjects affected / exposed	110 / 1524 (7.22%)	40 / 755 (5.30%)	63 / 957 (6.58%)
occurrences (all)	137	49	84
Constipation			
subjects affected / exposed	333 / 1524 (21.85%)	85 / 755 (11.26%)	203 / 957 (21.21%)
occurrences (all)	422	100	255
Diarrhoea			
subjects affected / exposed	388 / 1524 (25.46%)	107 / 755 (14.17%)	201 / 957 (21.00%)
occurrences (all)	626	144	308
Dyspepsia			
subjects affected / exposed	156 / 1524 (10.24%)	35 / 755 (4.64%)	102 / 957 (10.66%)
occurrences (all)	196	40	121
Eructation			
subjects affected / exposed	86 / 1524 (5.64%)	4 / 755 (0.53%)	38 / 957 (3.97%)
occurrences (all)	96	4	52
Flatulence			
subjects affected / exposed	81 / 1524 (5.31%)	22 / 755 (2.91%)	29 / 957 (3.03%)
occurrences (all)	94	25	35
Gastrooesophageal reflux disease			

subjects affected / exposed	101 / 1524 (6.63%)	18 / 755 (2.38%)	47 / 957 (4.91%)
occurrences (all)	112	19	50
Nausea			
subjects affected / exposed	622 / 1524 (40.81%)	128 / 755 (16.95%)	418 / 957 (43.68%)
occurrences (all)	974	170	616
Vomiting			
subjects affected / exposed	300 / 1524 (19.69%)	42 / 755 (5.56%)	172 / 957 (17.97%)
occurrences (all)	476	55	267
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	112 / 1524 (7.35%)	60 / 755 (7.95%)	34 / 957 (3.55%)
occurrences (all)	133	87	35
Oropharyngeal pain			
subjects affected / exposed	74 / 1524 (4.86%)	44 / 755 (5.83%)	31 / 957 (3.24%)
occurrences (all)	81	52	34
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	186 / 1524 (12.20%)	97 / 755 (12.85%)	38 / 957 (3.97%)
occurrences (all)	231	134	41
Back pain			
subjects affected / exposed	198 / 1524 (12.99%)	118 / 755 (15.63%)	77 / 957 (8.05%)
occurrences (all)	283	159	97
Pain in extremity			
subjects affected / exposed	108 / 1524 (7.09%)	54 / 755 (7.15%)	25 / 957 (2.61%)
occurrences (all)	127	64	27
Infections and infestations			
Bronchitis			
subjects affected / exposed	114 / 1524 (7.48%)	62 / 755 (8.21%)	35 / 957 (3.66%)
occurrences (all)	139	80	41
Gastroenteritis			
subjects affected / exposed	138 / 1524 (9.06%)	46 / 755 (6.09%)	48 / 957 (5.02%)
occurrences (all)	171	53	53
Influenza			

subjects affected / exposed	181 / 1524 (11.88%)	80 / 755 (10.60%)	65 / 957 (6.79%)
occurrences (all)	249	123	84
Nasopharyngitis			
subjects affected / exposed	404 / 1524 (26.51%)	210 / 755 (27.81%)	193 / 957 (20.17%)
occurrences (all)	764	408	290
Sinusitis			
subjects affected / exposed	129 / 1524 (8.46%)	65 / 755 (8.61%)	84 / 957 (8.78%)
occurrences (all)	174	111	99
Upper respiratory tract infection			
subjects affected / exposed	236 / 1524 (15.49%)	120 / 755 (15.89%)	101 / 957 (10.55%)
occurrences (all)	389	213	122
Urinary tract infection			
subjects affected / exposed	123 / 1524 (8.07%)	43 / 755 (5.70%)	48 / 957 (5.02%)
occurrences (all)	176	62	60
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	169 / 1524 (11.09%)	27 / 755 (3.58%)	102 / 957 (10.66%)
occurrences (all)	181	28	111
Hypoglycaemia			
subjects affected / exposed	295 / 1524 (19.36%)	35 / 755 (4.64%)	176 / 957 (18.39%)
occurrences (all)	637	52	302

Non-serious adverse events	Without Pre-Diabetes - Liraglutide Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	345 / 487 (70.84%)		
Investigations			
Lipase increased			
subjects affected / exposed	10 / 487 (2.05%)		
occurrences (all)	10		
Vascular disorders			
Hypertension			
subjects affected / exposed	13 / 487 (2.67%)		
occurrences (all)	13		
Nervous system disorders			

Dizziness			
subjects affected / exposed	19 / 487 (3.90%)		
occurrences (all)	20		
Headache			
subjects affected / exposed	58 / 487 (11.91%)		
occurrences (all)	80		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	27 / 487 (5.54%)		
occurrences (all)	31		
Injection site haematoma			
subjects affected / exposed	42 / 487 (8.62%)		
occurrences (all)	45		
Oedema peripheral			
subjects affected / exposed	6 / 487 (1.23%)		
occurrences (all)	7		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	19 / 487 (3.90%)		
occurrences (all)	22		
Abdominal pain upper			
subjects affected / exposed	18 / 487 (3.70%)		
occurrences (all)	20		
Constipation			
subjects affected / exposed	44 / 487 (9.03%)		
occurrences (all)	52		
Diarrhoea			
subjects affected / exposed	46 / 487 (9.45%)		
occurrences (all)	58		
Dyspepsia			
subjects affected / exposed	14 / 487 (2.87%)		
occurrences (all)	16		
Eructation			
subjects affected / exposed	2 / 487 (0.41%)		
occurrences (all)	2		
Flatulence			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Gastrooesophageal reflux disease</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nausea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vomiting</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>15 / 487 (3.08%)</p> <p>17</p> <p>8 / 487 (1.64%)</p> <p>8</p> <p>78 / 487 (16.02%)</p> <p>96</p> <p>25 / 487 (5.13%)</p> <p>29</p>		
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Oropharyngeal pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>22 / 487 (4.52%)</p> <p>23</p> <p>21 / 487 (4.31%)</p> <p>22</p>		
<p>Musculoskeletal and connective tissue disorders</p> <p>Arthralgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Back pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pain in extremity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>23 / 487 (4.72%)</p> <p>29</p> <p>41 / 487 (8.42%)</p> <p>50</p> <p>22 / 487 (4.52%)</p> <p>24</p>		
<p>Infections and infestations</p> <p>Bronchitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Gastroenteritis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Influenza</p>	<p>26 / 487 (5.34%)</p> <p>27</p> <p>24 / 487 (4.93%)</p> <p>32</p>		

subjects affected / exposed	26 / 487 (5.34%)		
occurrences (all)	37		
Nasopharyngitis			
subjects affected / exposed	110 / 487 (22.59%)		
occurrences (all)	166		
Sinusitis			
subjects affected / exposed	35 / 487 (7.19%)		
occurrences (all)	47		
Upper respiratory tract infection			
subjects affected / exposed	54 / 487 (11.09%)		
occurrences (all)	68		
Urinary tract infection			
subjects affected / exposed	15 / 487 (3.08%)		
occurrences (all)	19		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	16 / 487 (3.29%)		
occurrences (all)	17		
Hypoglycaemia			
subjects affected / exposed	29 / 487 (5.95%)		
occurrences (all)	37		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 September 2008	In-use time changed from 1 month to 14 days. Minor errors in protocol, flowcharts, appendices corrected.
22 May 2009	Mental health questionnaires implemented at all visits, study extended with 4 weeks to allow for 52 weeks of exposure of the maximal dose (3.0 mg), Hypo Section updated – hypo page implemented for subjects developing diabetes, medical event of special interest (MESI) Section updated, adjudication panel implemented, thyroid-stimulating hormone measured during the whole duration of the trial.
01 February 2011	Protocol updated according to United States Food and Drug Administration (U.S. FDA) requirements and Novo Nordisk template and procedures. Change had also been made to the subject information/informed consent (SI/IC)- 56-week, 160-week and SI/IC pharmacokinetic (PK) sub-study. A new SI/IC had been implemented for genetic testing. Protocol appendices I (Calcitonin Monitoring Committee – Screening of Calcitonin Levels) and J (MESI) added.
05 October 2011	Global update of master SI/IC and protocol.
20 April 2012	Update of safety text in protocol and SI/IC.
10 December 2013	Update of safety text in protocol and SI/IC. Requirement that fasting plasma glucose (FPG) values meeting the definition of a hypoglycaemic episode should be recorded as an adverse event. Reporting timelines for MESIs was changed. Change in Attachment I. Minor updates of various parts of protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

A potential limitation was the proportion of subjects who drop out during the trial, resulting in potentially biased estimates.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/26833744>

<http://www.ncbi.nlm.nih.gov/pubmed/26132939>

<http://www.ncbi.nlm.nih.gov/pubmed/26418188>

<http://www.ncbi.nlm.nih.gov/pubmed/26744025>