Clinical trial results:
A randomized, double-blind, dose-finding study to evaluate the change in weight after 24 weeks treatment with 8 doses of LIK066 compared to placebo in obese or overweight adults, followed by 24 weeks treatment with 2 doses of LIK066 and placebo

Summary

EudraCT number	2016-002868-14
Trial protocol	SK CZ AT HU GB
Global end of trial date	02 August 2018

Results information

Result version number	v1 (current)
This version publication date	22 August 2019
First version publication date	22 August 2019

Trial information

Trial identification

Sponsor protocol code	CLIK066B2201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03100058
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharmaceuticals
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma, AG, +41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, +41 613241111, Novartis.email@novartis.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	02 August 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the dose-response signal and assess the dose-response relationship of 2 dose regimens of LIK066 (2.5 mg, 10 mg, 50 mg and 150 mg qd, 2.5 mg, 5 mg, 25 mg and 50 mg twice daily (bid)) as measured by the percent change from baseline (BL) in body weight relative to placebo after 24 weeks of treatment.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 May 2017
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	Austria: 39
Country: Number of subjects enrolled	Canada: 41
Country: Number of subjects enrolled	Czech Republic: 49
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	Hungary: 48
Country: Number of subjects enrolled	Slovakia: 27
Country: Number of subjects enrolled	United States: 239
Worldwide total number of subjects	460
EEA total number of subjects	180

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)	387
From 65 to 84 years	73
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Overall, 674 patients were screened. Of the 460 patients who were randomized to the study, the majority (85.7%) completed Epoch 3. Of the 394 patients who completed Epoch 3 and entered Epoch 4, the majority (93.1%) completed the Epoch 4 study period.

Pre-assignment

Screening details:

Overall, 674 patients were screened. Of the 460 patients who were randomized to the study, the majority (85.7%) completed Epoch 3. Of the 394 patients who completed Epoch 3 and entered Epoch 4, the majority (93.1%) completed the Epoch 4 study period.

Period 1

Period 1 title	Epoch 3
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	LIK066 2.5mg qd (Epoch 3)

Arm description:

LIK066 2.5mg qd (once daily) dosing frequency for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

2.5mg qd/oral tablets/24 weeks

Arm title	LIK066 10mg qd (Epoch 3)

Arm description:

LIK066 10mg qd (once daily) dosing frequency for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

10mg qd/oral tablets/24 weeks

Arm title	LIK066 50mg qd (Epoch 3)

Arm description:

LIK066 50mg qd (once daily) dosing frequency for 24 weeks

Arm type	Experimental

Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
50mg qd/oral tablets/24 weeks

Arm title	LIK066 150mg qd (Epoch 3)

Arm description:
LIK066 150mg qd (once daily) dosing frequency for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
150mg qd /oral tablets/24 weeks

Arm title	LIK066 2.5mg bid (Epoch 3)

Arm description:
LIK066 2.5mg bid (twice daily) dosing frequency for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
2.5 mg bid/oral tablets/24 weeks

Arm title	LIK066 5mg bid (Epoch 3)

Arm description:
LIK066 5mg bid (twice daily) dosing frequency for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
5mg bid/oral tablets/24 weeks

Arm title	LIK066 25mg bid (Epoch 3)

Arm description:
LIK066 25mg bid (twice daily) dosing frequency for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details: 25mg bid/oral tablets/24 weeks	

Arm title	LIK066 50mg bid (Epoch 3)
Arm description: LIK066 50mg bid (twice daily) dosing frequency for 24 weeks	
Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 50mg bid/oral tablets/24 weeks	
Arm title	Placebo (Epoch 3)
Arm description: Matching placebo tablets for 24 weeks	
Arm type	Placebo
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: Placebo/oral tablets/24 weeks	

Number of subjects in period 1	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)
Started	38	38	38
Completed	35	31	29
Not completed	3	7	9
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	2	4	3
Physician decision	-	-	-
Adverse event, non-fatal	-	-	4
Pregnancy	1	-	-
Lost to follow-up	-	1	1
non-compliance with study treatment	-	1	1
Protocol deviation	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	LIK066 150mg qd (Epoch 3)	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)

Started	77	38	39
Completed	63	36	37
Not completed	14	2	2
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	4	1	1
Physician decision	1	-	-
Adverse event, non-fatal	8	1	-
Pregnancy	-	-	-
Lost to follow-up	-	-	-
non-compliance with study treatment	-	-	1
Protocol deviation	1	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)	Placebo (Epoch 3)
Started	38	76	78
Completed	30	60	73
Not completed	8	16	5
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	4	2
Physician decision	-	1	-
Adverse event, non-fatal	3	11	2
Pregnancy	-	-	-
Lost to follow-up	1	-	1
non-compliance with study treatment	1	-	-
Protocol deviation	1	-	-
Lack of efficacy	1	-	-

Period 2

Period 2 title	Epoch 4
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	No

Arm title	LIK066 qd/LIK066 25 mg qd (Epoch 4)
Arm description:	
LIK066 qd (once daily) patients who entered Epoch 4 and received LIK066 25 mg qd	
Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
LIK066 25 mg qd/oral tablets/24 weeks	
Arm title	LIK066 bid/LIK066 35 mg qd
Arm description:	
LIK066 bid patients who entered Epoch 4 and received LIK066 35 mg qd	
Arm type	Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
LIK066 35 mg qd/oral tablets/24 weeks	
Arm title	Placebo/LIK066 25 mg qd
Arm description:	
Matching placebo tablets for 24 weeks	
Arm type	Placebo/Experimental
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
LIK066 325 mg qd	
Arm title	Placebo qd (Epoch 4)
Arm description:	
Placebo patients who entered Epoch 4 and received matching Placebo tablets qd	
Arm type	Placebo
Investigational medicinal product name	Licogliflozin
Investigational medicinal product code	LIK066
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
Placebo/oral tablets/24 weeks	

Number of subjects in period 2	LIK066 qd/LIK066 25 mg qd (Epoch 4)	LIK066 bid/LIK066 35 mg qd	Placebo/LIK066 25 mg qd
Started	158	163	39
Completed	153	148	36
Not completed	5	15	3
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	-	4	2
Adverse event, non-fatal	4	7	-
Pregnancy	-	-	-
Lost to follow-up	-	3	1
non-compliance with study treatment	1	-	-

Number of subjects in period 2	Placebo qd (Epoch 4)
Started	34
Completed	30
Not completed	4
Adverse event, serious fatal	-
Consent withdrawn by subject	1
Adverse event, non-fatal	2
Pregnancy	1
Lost to follow-up	-
non-compliance with study treatment	-

Baseline characteristics

Reporting groups	
Reporting group title	LIK066 2.5mg qd (Epoch 3)
Reporting group description:	
LIK066 2.5mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 10mg qd (Epoch 3)
Reporting group description:	
LIK066 10mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 50mg qd (Epoch 3)
Reporting group description:	
LIK066 50mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 150mg qd (Epoch 3)
Reporting group description:	
LIK066 150mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 2.5mg bid (Epoch 3)
Reporting group description:	
LIK066 2.5mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 5mg bid (Epoch 3)
Reporting group description:	
LIK066 5mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 25mg bid (Epoch 3)
Reporting group description:	
LIK066 25mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 50mg bid (Epoch 3)
Reporting group description:	
LIK066 50mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	Placebo (Epoch 3)
Reporting group description:	
Matching placebo tablets for 24 weeks	

Reporting group values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)
Number of subjects	38	38	38
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	32	34	29
From 65-84 years	6	4	9
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	51.3	53.2	52.9

standard deviation	± 12.20	± 10.08	± 13.60

Sex: Female, Male Units: Subjects			
Female	23	27	25
Male	15	11	13
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	4	5
White	30	33	33
More than one race	0	0	0
Unknown or Not Reported	1	1	0

Reporting group values	LIK066 150mg qd (Epoch 3)	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)
Number of subjects	77	38	39
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	64	30	35
From 65-84 years	13	8	4
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	51.1	53.4	49.8
standard deviation	± 12.94	± 12.28	± 11.50
Sex: Female, Male Units: Subjects			
Female	44	20	24
Male	33	18	15
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	0	2
Native Hawaiian or Other Pacific Islander	2	0	0
Black or African American	5	2	3
White	67	36	32
More than one race	0	0	0
Unknown or Not Reported	1	0	2

Reporting group values	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)	Placebo (Epoch 3)
Number of subjects	38	76	78
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	35	62	66
From 65-84 years	3	14	12
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	49.7	52.9	51.1
standard deviation	± 11.93	± 11.87	± 13.27
Sex: Female, Male			
Units: Subjects			
Female	26	49	45
Male	12	27	33
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	2	2
Asian	0	5	1
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	4	6	8
White	34	63	64
More than one race	0	0	0
Unknown or Not Reported	0	0	2

Reporting group values	Total		
Number of subjects	460		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	387		
From 65-84 years	73		
85 years and over	0		
Age Continuous			
Units: Years			
arithmetic mean			

standard deviation	-		

Sex: Female, Male Units: Subjects			
Female	283		
Male	177		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	6		
Asian	10		
Native Hawaiian or Other Pacific Islander	3		
Black or African American	42		
White	392		
More than one race	0		
Unknown or Not Reported	7		

Subject analysis sets

Subject analysis set title	LIK066 qd/LIK066 25mg qd (Epoch 4)
Subject analysis set type	Per protocol

Subject analysis set description:

Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily

Subject analysis set title	LIK066 bid/LIK066 35mg qd (Epoch 4)
Subject analysis set type	Per protocol

Subject analysis set description:

Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily

Subject analysis set title	Placebo/LIK066 25mg qd (Epoch 4)
Subject analysis set type	Per protocol

Subject analysis set description:

Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily

Subject analysis set title	Placebo/Placebo (Epoch 4)
Subject analysis set type	Per protocol

Subject analysis set description:

Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily

Reporting group values	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Number of subjects	158	163	39
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	132	138	35
From 65-84 years	26	24	4
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex: Female, Male			
Units: Subjects			
Female	96	99	22
Male	62	63	17
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	2	2	0
Asian	13	14	2
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	13	14	2
White	138	137	35
More than one race	0	0	0
Unknown or Not Reported	2	2	2

Reporting group values	Placebo/Placebo (Epoch 4)		
Number of subjects	34		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	26		
From 65-84 years	8		
85 years and over	0		
Age Continuous			
Units: Years			
arithmetic mean			
standard deviation	±		
Sex: Female, Male			
Units: Subjects			
Female	20		
Male	14		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	2		

Asian	3		
Native Hawaiian or Other Pacific Islander	1		
Black or African American	3		
White	27		
More than one race	0		
Unknown or Not Reported	0		

End points

End points reporting groups

Reporting group title	LIK066 2.5mg qd (Epoch 3)
Reporting group description: LIK066 2.5mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 10mg qd (Epoch 3)
Reporting group description: LIK066 10mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 50mg qd (Epoch 3)
Reporting group description: LIK066 50mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 150mg qd (Epoch 3)
Reporting group description: LIK066 150mg qd (once daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 2.5mg bid (Epoch 3)
Reporting group description: LIK066 2.5mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 5mg bid (Epoch 3)
Reporting group description: LIK066 5mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 25mg bid (Epoch 3)
Reporting group description: LIK066 25mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	LIK066 50mg bid (Epoch 3)
Reporting group description: LIK066 50mg bid (twice daily) dosing frequency for 24 weeks	
Reporting group title	Placebo (Epoch 3)
Reporting group description: Matching placebo tablets for 24 weeks	
Reporting group title	LIK066 qd/LIK066 25 mg qd (Epoch 4)
Reporting group description: LIK066 qd (once daily) patients who entered Epoch 4 and received LIK066 25 mg qd	
Reporting group title	LIK066 bid/LIK066 35 mg qd
Reporting group description: LIK066 bid patients who entered Epoch 4 and received LIK066 35 mg qd	
Reporting group title	Placebo/LIK066 25 mg qd
Reporting group description: Matching placebo tablets for 24 weeks	
Reporting group title	Placebo qd (Epoch 4)
Reporting group description: Placebo patients who entered Epoch 4 and received matching Placebo tablets qd	
Subject analysis set title	LIK066 qd/LIK066 25mg qd (Epoch 4)
Subject analysis set type	Per protocol
Subject analysis set description: Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily	
Subject analysis set title	LIK066 bid/LIK066 35mg qd (Epoch 4)
Subject analysis set type	Per protocol

Subject analysis set description:

Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily

Subject analysis set title	Placebo/LIK066 25mg qd (Epoch 4)
Subject analysis set type	Per protocol

Subject analysis set description:

Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily

Subject analysis set title	Placebo/Placebo (Epoch 4)
Subject analysis set type	Per protocol

Subject analysis set description:

Between week 24 to week 48, the patients who received a once daily regimen in the first 24 weeks will receive Dose A of LIK066 once daily and patients who received a twice daily regimen in the first 24 weeks will receive Dose B LIK066 once daily

Primary: Percent change from baseline in body weight at 24 weeks

End point title	Percent change from baseline in body weight at 24 weeks

End point description:

Dose-response relationship of two dose regimens of LIK066 as measured by the percent change from baseline in body weight relative to placebo after 24 weeks of treatment

End point type	Primary

End point timeframe:

Baseline, Week 24 (Epoch 3)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: Percent change				
number (confidence interval 95%)	-1.24 (-2.50 to -0.45)	-2.04 (-3.36 to -0.88)	-3.52 (-4.62 to -1.87)	-4.37 (-5.36 to -3.37)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: Percent change				
number (confidence interval 95%)	-1.67 (-2.61 to -0.27)	-2.51 (-3.94 to -1.32)	-4.06 (-5.52 to -2.87)	-4.47 (-5.49 to -3.48)

End point values	Placebo (Epoch 3)			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Percent change				

number (confidence interval 95%)	-0.63 (-1.56 to 0.37)			

Statistical analyses

Statistical analysis title	LIK066 2.5 mg qd vs. Placebo
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.17
upper limit	-0.29

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.36
upper limit	-0.5

Statistical analysis title	LIK066 50mg qd vs Placebo
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.86
upper limit	-1.75

Statistical analysis title	LIK066 150mg qd vs Placebo
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-4.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.39
upper limit	-3.44

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.53
upper limit	-0.25

Statistical analysis title	LIK066 2.5mg bid vs Placebo

Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.11
upper limit	-1.36

Statistical analysis title	LIK066 25mg bid vs Placebo
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-4.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.54
upper limit	-2.68

Statistical analysis title	LIK066 50mg bid vs Placebo
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-4.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.54
upper limit	-3.43

Secondary: Number of subjects with response rate according to percent decrease in body weight for overall study

End point title	Number of subjects with response rate according to percent decrease in body weight for overall study

End point description:

Responder rates according to percentage decrease in body weight either ≥ 5 % or ≥ 10 % from baseline

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: Percentage				
number (not applicable)				
>=5%	26.3	15.8	34.2	42.9
>=10%	5.3	5.3	5.3	6.5

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	37	75
Units: Percentage				
number (not applicable)				
>=5%	15.8	20.5	37.8	45.3
>=10%	5.3	2.6	10.8	9.3

End point values	Placebo (Epoch 3)			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Percentage				
number (not applicable)				
>=5%	12.8			
>=10%	3.8			

Statistical analyses

Statistical analysis title	LIK066 2.5mg qd vs Placebo

Statistical analysis description:

>=5%

Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.099
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	2.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	6.67

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: >=5%	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.779
Method	ANCOVA
Parameter estimate	Log odds ratio
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	3.84

Statistical analysis title	LIk066 50mg qd vs Placebo
Statistical analysis description: >=5%	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.011
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	3.69

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.35
upper limit	10.11

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: >=5%	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	5.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.41
upper limit	12.88

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description: >=5%	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.812
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	3.74

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: >=5%	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.229
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	5.69

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: >=5%	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	4.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.61
upper limit	11.46

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: >=5%	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	6.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.72
upper limit	14.93

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.943
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	12.41

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.465
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	2.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	15.77

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.696
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	17.15

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.389
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	2.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	12.1

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.976
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	11.87

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.986
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	11.7

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.181
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	3.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	22.18

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: >=10%	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	3.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	20.54

Secondary: Number of subjects with response rate according to percent decrease in body weight for Subgroups

End point title	Number of subjects with response rate according to percent decrease in body weight for Subgroups

End point description:

Responder rates according to percentage decrease in body weight either ≥ 5 % or ≥ 10 % from baseline for dysglycemic, normoglycemic, Type 2 Diabetes Mellitus (T2DM)

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: Percentage				
number (not applicable)				
Dysglycemic (>=5%)	31.3	25.0	40.0	48.4
Normoglycemic (>=5%)	44.4	11.1	44.4	47.4
Type 2 Diabetes Mellitus (T2DM) (>=5%)	7.7	15.4	28.6	37.0

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	37	75
Units: Percentage				
number (not applicable)				
Dysglycemic (>=5%)	6.7	37.5	40.0	41.9
Normoglycemic (>=5%)	11.1	11.1	55.6	52.9
Type 2 Diabetes Mellitus (T2DM) (>=5%)	28.6	14.3	30.8	44.4

End point values	Placebo (Epoch 3)			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Percentage				
number (not applicable)				
Dysglycemic (>=5%) Normoglycemic (>=5%) Type 2 Diabetes Mellitus (T2DM) (>=5%)	9.7 20.0 14.8			

Statistical analyses

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: >=5% (Dysglycemic)	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.048
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	6.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	38.76

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: >=5% (Dsyglycemic)	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.171
Method	ANCOVA
Parameter estimate	Log odds ratio
Point estimate	3.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	28.03

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: >=5% (Dysglycemic)	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.041
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	7.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	47.27

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: >=5% (Dysglycemic)	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	11.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.32
upper limit	60.93

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description: >=5% (Dysglycemic)	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.976
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	11.72

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: >=5% (Dysglycemic)	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.022
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	8.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.37
upper limit	56.44

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: >=5% (Dysglycemic)	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.032
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	7.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	46.99

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: >=5% (Dysglycemic)	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	11.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.11
upper limit	60.46

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.227
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	3.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	21.28

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.763
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	7.85

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.095
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	4.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	28.7

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.033
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	5.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.14
upper limit	24.83

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.788
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	8.1

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.751
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	7.62

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.027
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	8.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.27
upper limit	51.09

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: >=5% (Normoglycemic)	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.023
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	6.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	34

Statistical analysis title	LIK066 2.5 mg qd vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.528
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	4.78

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.958
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	6.68

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.546
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	9.49

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.098
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	3.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	11.75

Statistical analysis title	LIK066 2.5 mg bid vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.563
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	8.7

Statistical analysis title	LIK066 5 mg bid vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.61
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	5.38

Statistical analysis title	LIK066 25 mg bid vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.528
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	1.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	9.16

Statistical analysis title	LIK066 50 mg bid vs Placebo
Statistical analysis description: >=5% (T2DM)	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.023
Method	ANCOVA
Parameter estimate	Odds ratio (OR)
Point estimate	4.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	16.9

Secondary: Change from baseline on waist circumference

End point title	Change from baseline on waist circumference

End point description:

Waist circumference will be measured to the nearest 0.1cm in a standing position, at the end of a normal expiration, using a tape at the level of the iliac crest.

End point type	Secondary

End point timeframe:

Baseline, Week 24 (Epoch 3), Week 24 to Week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: Percentage Change				
arithmetic mean (confidence interval 95%)	-2.1 (-3.87 to -0.31)	-2.7 (-4.55 to -0.92)	-3.7 (-5.55 to -1.82)	-5.6 (-6.84 to -4.35)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: Percentage Change				
arithmetic mean (confidence interval 95%)	-2.7 (-4.47 to -0.91)	-4.3 (-6.07 to -2.57)	-4.8 (-6.61 to -2.98)	-4.6 (-5.89 to -3.31)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: Percentage Change				
arithmetic mean (confidence interval 95%)	-1.3 (-2.54 to -0.05)	-0.4 (-1.25 to 0.36)	-0.7 (-1.53 to 0.10)	-2.1 (-3.73 to -0.38)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: Percentage Change				
arithmetic mean (confidence interval 95%)	0.4 (-1.37 to 2.20)			

Statistical analyses

Statistical analysis title	LIK066 2.5 mg qd vs Placebo
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.47
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.96
upper limit	1.37

Statistical analysis title	LIK066 10mg qd vs Placebo
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.199
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.64
upper limit	0.76

Statistical analysis title	LIK066 150mg qd vs Placebo
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.64
upper limit	0.76

Statistical analysis title	LIK066 2.5mg bid vs Placebo

Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.206
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.56
upper limit	0.77

Statistical analysis title	LIK066 5mg bid vs Placebo
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.18
upper limit	-0.88

Statistical analysis title	LIK066 50mg bid vs Placebo
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	-1.51

Statistical analysis title	LIK066 25mg bid vs Placebo
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-3.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	-1.3

Statistical analysis title	LIK066 bid/LIK066 35mg qd vs Placebo
Comparison groups	LIK066 bid/LIK066 35mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.259
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	0.84

Statistical analysis title	LIK066 qd/LIK066 25 mg qd vs Placebo
Comparison groups	LIK066 qd/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.391
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.82
upper limit	1.1

Statistical analysis title	Placebo/LIK066 25mg qd vs Placebo
Comparison groups	Placebo/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.048
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.91
upper limit	-0.02

Secondary: Change from baseline in fasting plasma glucose (FPG) in Type 2 Diabetes Mellitus Patients (T2DM)

End point title	Change from baseline in fasting plasma glucose (FPG) in Type 2 Diabetes Mellitus Patients (T2DM)
End point description:	
FPG will be measured from a blood sample obtained after an overnight fast (at least 8h after last evening food intake).	
End point type	Secondary
End point timeframe:	
Baseline, Week 24 (Epoch 3), Week 24 to Week 48 (Epoch 4)	

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: mmol/L				
arithmetic mean (confidence interval 95%)	1.9 (0.55 to 3.19)	-0.1 (-1.46 to 1.27)	-1.2 (-2.60 to 0.26)	-0.8 (-1.70 to 0.16)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: mmol/L				
arithmetic mean (confidence interval 95%)	-0.5 (-1.80 to 0.86)	-1.1 (-2.37 to 0.27)	-0.9 (-2.28 to 0.46)	-1.0 (-1.96 to -0.13)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: mmol/L				
arithmetic mean (confidence interval 95%)	0.9 (-0.06 to 1.81)	-0.1 (-0.64 to 0.35)	-0.3 (-0.79 to 0.22)	-0.1 (-1.14 to 0.84)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: mmol/L				
arithmetic mean (confidence interval 95%)	0.6 (-0.54 to 1.73)			

Statistical analyses

Statistical analysis title	LIK066 2.5mg qd va Placebo
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.225
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	2.61

Statistical analysis title	LIK066 10mg qd vs Placebo
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.247
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.62
upper limit	0.68

Statistical analysis title	LIK066 50mg qd vs Placebo
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.019
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.75
upper limit	-0.34

Statistical analysis title	LIK066 150mg qd vs Placebo
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.015
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.96
upper limit	-0.33

Statistical analysis title	LIK066 2.5mg bid vs Placebo

Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.106
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.97
upper limit	0.29

Statistical analysis title	LIK066 5mg bid vs Placebo
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.02
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.54
upper limit	-0.31

Statistical analysis title	LIK066 25mg bid vs Placebo
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.035
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.44
upper limit	-0.12

Statistical analysis title	LIK066 50mg bid vs Placebo
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.22
upper limit	-0.61

Secondary: Change from baseline in glycated hemoglobin A1c (HbA1c) in Type 2 Diabetes Mellitus patients (T2DM)

End point title	Change from baseline in glycated hemoglobin A1c (HbA1c) in Type 2 Diabetes Mellitus patients (T2DM)

End point description:

HbA1c will be measured from a blood sample obtained at indicated visits and will be analyzed at a central laboratory.

End point type	Secondary

End point timeframe:

Baseline, Week 24 (Epoch 3), Week 24 to week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: Percentage change				
arithmetic mean (confidence interval 95%)	0.1 (-0.23 to 0.45)	-0.5 (-0.82 to -0.13)	-0.9 (-1.24 to -0.50)	-0.7 (-0.92 to -0.44)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: Percentage change				
arithmetic mean (confidence interval 95%)	-0.3 (-0.68 to 0.00)	-0.5 (-0.83 to -0.15)	-0.6 (-0.98 to -0.28)	-0.6 (-0.87 to -0.40)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: Percentage change				
arithmetic mean (confidence interval 95%)	-0.3 (-0.50 to -0.02)	0.2 (0.03 to 0.38)	0.0 (-0.13 to 0.22)	-0.1 (-0.49 to 0.24)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: Percentage change				
arithmetic mean (confidence interval 95%)	0.3 (-0.07 to 0.71)			

Statistical analyses

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.082
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.79

Statistical analysis title	LIK066 10mg qd vs Placebo
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.319
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-0.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	0.21

Statistical analysis title	LIK066 50mg qd vs Placebo
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.008
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.05
upper limit	-0.16

Statistical analysis title	LIK066 150mg qd vs Placebo
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.015
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	-0.08

Statistical analysis title	LIK066 5mg bid vs Placebo
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.28
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.65
upper limit	0.19

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.707
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.34

Statistical analysis title	LIK066 25mg bid vs Placebo
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.086
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	0.05

Statistical analysis title	LIK066 50mg bid vs Placebo

Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.03
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.72
upper limit	-0.04

Secondary: Change from baseline in mean sitting systolic blood pressure (msSBP) and mean sitting diastolic blood pressure (msDBP)

End point title	Change from baseline in mean sitting systolic blood pressure (msSBP) and mean sitting diastolic blood pressure (msDBP)

End point description:

At each study visit (baseline, week 24, Week 48), after the subject has been sitting for 5 minutes with the back supported and both feet placed on the floor, SBP and DBP will be measured

End point type	Secondary

End point timeframe:

Baseline, Week 24 (Epoch 3) Week 24 to Week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: mmHg				
arithmetic mean (confidence interval 95%)				
systolic blood pressure (SBP)	-1.2 (-4.38 to 1.93)	-1.5 (-4.38 to 1.93)	-4.9 (-8.30 to -1.52)	-1.2 (-3.38 to 1.06)
diastolic blood pressure (DBP)	-0.2 (-2.37 to 2.00)	0.1 (-2.21 to 2.40)	-2.3 (-4.62 to 0.07)	-1.3 (-2.82 to 0.26)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: mmHg				
arithmetic mean (confidence interval 95%)				
systolic blood pressure (SBP)	-0.7 (-3.86 to 2.43)	0.8 (-2.38 to 3.88)	-2.6 (-5.82 to 0.69)	-1.8 (-4.15 to 0.48)

diastolic blood pressure (DBP)	0.8 (-1.35 to 3.02)	-1.4 (-3.57 to 0.78)	0.3 (-1.99 to 2.54)	-1.7 (-3.26 to -0.06)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: mmHg				
arithmetic mean (confidence interval 95%)				
systolic blood pressure (SBP)	1.6 (-0.67 to 3.80)	-0.9 (-2.66 to 0.79)	-1.6 (-3.39 to 0.10)	-5.6 (-9.22 to -2.06)
diastolic blood pressure (DBP)	0.5 (-1.03 to 2.08)	-0.6 (-1.69 to 0.56)	-1.2 (-2.30 to -0.04)	-2.0 (-4.33 to 0.34)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: mmHg				
arithmetic mean (confidence interval 95%)				
systolic blood pressure (SBP)	0.8 (-2.97 to 4.65)			
diastolic blood pressure (DBP)	0.6 (-1.89 to 3.06)			

Statistical analyses

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: SBP	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.156
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.64
upper limit	1.07

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description:	
SBP	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.127
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.11
upper limit	0.89

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description:	
SBP	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.52
upper limit	-2.42

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description:	
SBP	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.089
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.86
upper limit	0.42

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description:	
SBP	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.245
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.12
upper limit	1.57

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description:	
SBP	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.678
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.65
upper limit	3.02

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description:	
SBP	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.04
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.07
upper limit	-0.19

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description:	
SBP	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.038
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.61
upper limit	-0.19

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.601
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.38
upper limit	1.96

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.76
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	2.34

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.051
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	0.01

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.105
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.98
upper limit	0.38

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.82
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.36
upper limit	2.98

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.157
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.58
upper limit	0.74

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.859
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.99
upper limit	2.49

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description:	
DBP	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.054
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.41
upper limit	0.04

Secondary: Change from baseline in 24-hour urinary glucose excretion

End point title	Change from baseline in 24-hour urinary glucose excretion

End point description:

Urinary glucose excretion will be measured from 24-hour urinary collection at indicated visits and will be analyzed at a central laboratory.

End point type	Secondary

End point timeframe:

Baseline, week 24 (Epoch 3), Week 24 to Week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: mmol/24hr				
arithmetic mean (confidence interval 95%)	208.6 (101.85 to 315.40)	134.6 (-8.69 to 277.85)	377.0 (206.19 to 547.90)	306.1 (199.59 to 412.62)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: mmol/24hr				
arithmetic mean (confidence interval 95%)	183.0 (32.37 to 333.70)	193.8 (82.22 to 305.31)	241.3 (135.13 to 347.30)	308.9 (198.27 to 419.53)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: mmol/24hr				
arithmetic mean (confidence interval 95%)	-17.8 (-94.20 to 58.61)	26.8 (-30.03 to 83.70)	122.5 (69.82 to 175.26)	248.0 (137.72 to 358.33)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: mmol/24hr				
arithmetic mean (confidence interval	-148.9			

95%)	(-269.62 to -28.10)

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Weight in the overall population and by subgroups (Epoch 4)

End point title	Change in Weight in the overall population and by subgroups (Epoch 4)

End point description:

Between -treatment analysis of percentage change from Week 24 in body weight (kg) at Week 48 (Epoch 4)

End point type	Secondary

End point timeframe:

Between Week 24 and Week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: kg				
arithmetic mean (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: kg				
arithmetic mean (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: kg				
arithmetic mean (confidence interval 95%)	0 (0 to 0)	-0.2 (-0.70 to 0.33)	-0.2 (-0.68 to 0.35)	-2.4 (-3.47 to -1.33)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: kg				
arithmetic mean (confidence interval 95%)	0.4 (-0.74 to 1.55)			

Statistical analyses

Statistical analysis title	LIK066 qd/LIK066 25mg qd vs Placebo
Comparison groups	LIK066 qd/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.355
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.84
upper limit	0.66

Statistical analysis title	Placebo/LIK066 25mg qd vs Placebo
Comparison groups	Placebo/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.36
upper limit	-1.24

Statistical analysis title	LIK066 bid/LIK066 35mg qd vs Placebo
Comparison groups	LIK066 bid/LIK066 35mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.373
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.83
upper limit	0.69

Secondary: Change from Baseline to Week 24 (Epoch 3) in the 24-hour urinary calcium excretion

End point title	Change from Baseline to Week 24 (Epoch 3) in the 24-hour urinary calcium excretion
End point description:	
Evaluation of 24-hour urinary calcium excretion after 24 week of treatment.	
End point type	Secondary
End point timeframe:	
Baseline, Week 24	

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: mmol/24hr				
arithmetic mean (standard deviation)				
Baseline	49.6 (± 25.08)	33.1 (± 29.65)	40.2 (± 21.55)	34.6 (± 17.56)
Week 24 (Timepoint 1)	48.8 (± 26.59)	38.1 (± 32.20)	39.8 (± 22.48)	40.1 (± 18.20)
Week 24 (Timepoint 2)	54.2 (± 29.34)	42.0 (± 29.99)	39.2 (± 20.24)	62.8 (± 34.26)
Week 24 (Timepoint 3)	5.4 (± 22.74)	3.9 (± 19.56)	-0.6 (± 12.07)	22.8 (± 28.42)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: mmol/24hr				
arithmetic mean (standard deviation)				
Baseline	44.7 (± 26.83)	43.6 (± 16.91)	38.0 (± 22.13)	47.9 (± 23.64)
Week 24 (Timepoint 1)	52.4 (± 32.78)	45.9 (± 15.41)	38.0 (± 22.13)	48.1 (± 21.93)

Week 24 (Timepoint 2)	51.2 (± 35.32)	54.6 (± 23.77)	37.9 (± 32.33)	53.0 (± 26.95)
Week 24 (Timepoint 3)	-1.2 (± 7.77)	8.7 (± 18.21)	-0.1 (± 14.39)	4.9 (± 26.20)

End point values	Placebo (Epoch 3)			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: mmol/24hr				
arithmetic mean (standard deviation)				
Baseline	43.0 (± 22.63)			
Week 24 (Timepoint 1)	44.7 (± 23.0)			
Week 24 (Timepoint 2)	52.2 (± 30.75)			
Week 24 (Timepoint 3)	7.5 (± 32.91)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline Week 24 to Week 48 (Epoch 4) in the 24-hour urinary calcium excretion

End point title	Change from Baseline Week 24 to Week 48 (Epoch 4) in the 24-hour urinary calcium excretion
End point description:	
Evaluation of 24-hour urinary calcium after 48 weeks of treatment	
End point type	Secondary
End point timeframe:	
Baseline, Week 24, Week 48	

End point values	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)	Placebo/Placebo (Epoch 4)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	158	163	39	34
Units: mmol/24hr				
arithmetic mean (standard deviation)				
Baseline	4.8 (± 3.02)	5.0 (± 2.84)	4.6 (± 0.91)	5.6 (± 4.07)
Week 48(Timepoint 1)	5.1 (± 307)	5.2 (± 2.95)	4.5 (± 0.95)	6.6 (± 4.55)
Week 48(Timepoint 2)	4.6 (± 2.33)	5.6 (± 4.55)	5.4 (± 3.65)	4.8 (± 2.10)
Week 48(Timepoint 3)	-0.5 (± 3.41)	0.4 (± 2.81)	0.9 (± 4.10)	-1.8 (± 3.26)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 (Epoch 3) in the 24-hour urinary phosphorus excretion

End point title	Change from Baseline to Week 24 (Epoch 3) in the 24-hour urinary phosphorus excretion

End point description:

Evaluation of 24-hour urinary phosphorus excretion after 24 weeks of treatment

End point type	Secondary

End point timeframe:

Week 24, Week 48

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: mmol/24hr				
arithmetic mean (standard deviation)				
Baseline	282.1 (± 128.10)	240.5 (± 74.64)	254.5 (± 105.70)	291.5 (± 175.10)
Week 24 (Timepoint 1)	284.0 (± 140.10)	239.7 (± 80.40)	260.9 (± 111.10)	275.0 (± 101.30)
Week 24 (Timepoint 2)	297.7 (± 117.40)	295.3 (± 95.60)	299.2 (± 145.50)	264.7 (± 74.84)
Week 24 (Timepoint 3)	13.0 (± 132.00)	55.6 (± 89.81)	38.3 (± 70.00)	-10.2 (± 103.60)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: mmol/24hr				
arithmetic mean (standard deviation)				
Baseline	284.0 (± 117.60)	241.8 (± 82.75)	277.0 (± 99.67)	293.7 (± 120.70)
Week 24 (Timepoint 1)	319.9 (± 32.78)	246.5 (± 84.19)	299.3 (± 79.06)	302.5 (± 121.30)
Week 24 (Timepoint 2)	317.8 (± 205.10)	341.6 (± 109.20)	260.5 (± 124.80)	289.3 (± 83.62)
Week 24 (Timepoint 3)	-2.1 (± 159.60)	95.1 (± 67.36)	-38.7 (± 107.80)	-13.2 (± 153.80)

End point values	Placebo (Epoch 3)			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: mmol/24hr				

arithmetic mean (standard deviation)				
Baseline	297.0 (± 145.10)			
Week 24 (Timepoint 1)	307.9 (± 145.90)			
Week 24 (Timepoint 2)	352.8 (± 159.30)			
Week 24 (Timepoint 3)	44.9 (± 177.60)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline Week 24 to Week 48 (Epoch 4) in the 24-hour urinary phosphorus excretion

End point title	Change from Baseline Week 24 to Week 48 (Epoch 4) in the 24-hour urinary phosphorus excretion
End point description:	
Evaluation of 24-hour urinary phosphorus excretion after 48 weeks of treatment	
End point type	Secondary
End point timeframe:	
Week 24, Week 48	

End point values	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)	Placebo/Placebo (Epoch 4)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	158	163	39	34
Units: mmol/24hr				
arithmetic mean (standard deviation)				
Baseline	27.6 (± 11.46)	30.5 (± 11.63)	28.6 (± 14.11)	40.2 (± 15.96)
Week 48 (Timepoint 1)	27.5 (± 11.73)	30.2 (± 11.85)	28.6 (± 14.11)	44.4 (± 17.60)
Week 48 (Timepoint 2)	24.7 (± 12.74)	31.1 (± 16.21)	31.0 (± 14.67)	29.0 (± 15.42)
Week 48(Timepoint 3)	-2.8 (± 11.44)	0.9 (± 14.52)	2.4 (± 17.33)	-15.5 (± 18.92)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in fasting lipid profile (lipoproteins)

End point title	Change from baseline in fasting lipid profile (lipoproteins)
End point description:	
Between-treatment analysis of change after 24 weeks of treatment and between Week 24 and Week 48	
End point type	Secondary

End point timeframe:
Baseline, Week 24, Week 24 to Week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: g/L				
arithmetic mean (confidence interval 95%)				
Apoliprotein A1	8.9 (4.26 to 13.61)	8.13 (3.27 to 13.30)	10.7 (5.38 to 15.97)	8.9 (5.55 to 12.21)
Apoliprotein B	2.9 (-5.32 to 11.08)	7.7 (-1.23 to 16.61)	3.3 (-6.06 to 12.72)	12.4 (6.57 to 18.32)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: g/L				
arithmetic mean (confidence interval 95%)				
Apoliprotein A1	5.3 (0.487 to 10.17)	8.1 (3.44 to 12.86)	6.7 (1.75 to 11.59)	11.0 (7.47 to 14.44)
Apoliprotein B	-0.4 (-8.91 to 8.18)	4.5 (-3.84 to 12.74)	2.3 (-6.36 to 10.98)	3.9 (-2.29 to 10.01)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: g/L				
arithmetic mean (confidence interval 95%)				
Apoliprotein A1	6.7 (3.41 to 10.06)	3.0 (0.92 to 5.10)	3.4 (1.22 to 5.51)	5.6 (1.35 to 9.89)
Apoliprotein B	5.8 (-0.03 to 11.69)	-1.7 (-4.39 to 1.08)	-2.4 (-5.23 to 0.38)	-2.3 (-7.85 to 3.31)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: g/L				

arithmetic mean (confidence interval 95%)				
Apoliprotein A1	-0.7 (-5.27 to 3.87)			
Apoliprotein B	-2.0 (-8.00 to 3.96)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in High sensitive C-reactive protein (hsCRP)

End point title	Change from baseline in High sensitive C-reactive protein (hsCRP)

End point description:

Between-treatment analysis of change after 24 weeks of treatment and between Week 24 and Week 48

End point type	Secondary

End point timeframe:

Baseline to Week 24, Week 24 to Week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: mg/L				
geometric mean (confidence interval 95%)	0.99 (0.78 to 1.25)	1.06 (0.83 to 1.36)	1.31 (1.01 to 1.69)	0.98 (0.83 to 1.16)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: mg/L				
geometric mean (confidence interval 95%)	1.02 (0.80 to 1.30)	0.93 (0.74 to 118)	1.00 (0.78 to 1.27)	0.98 (0.83 to 1.17)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: mg/L				
geometric mean (confidence interval 95%)	0.92 (0.78 to 1.09)	0.95 (0.85 to 1.06)	0.93 (0.83 to 1.04)	0.96 (0.77 to 1.20)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: mg/L				
geometric mean (confidence interval 95%)	1.07 (0.84 to 1.36)			

Statistical analyses

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.632
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.42

Statistical analysis title	LIK066 10mg qd vs Placebo
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.352
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.55

Statistical analysis title	LIK066 50mg qd vs Placeb

Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.027
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.92

Statistical analysis title	LIK066 150mg qd vs Placebo
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.587
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.35

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.508
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.47

Statistical analysis title	LIK066 5mg bid vs Placebo
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.945
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.34

Statistical analysis title	LIK066 25mg bid vs Placebo
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.602
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.45

Statistical analysis title	LIK066 50mg bid vs Placebo
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.612
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.35

Statistical analysis title	LIK066 qd/LIK066 25mg qd vs Placebo
Comparison groups	LIK066 qd/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.382
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.16

Statistical analysis title	LIK066 bid/LIK066 35mg qd vs Placebo
Comparison groups	LIK066 bid/LIK066 35mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.31
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.14

Statistical analysis title	Placebo/LIK066 25mg qd vs Placebo
Comparison groups	Placebo/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.525
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.25

Secondary: Change from baseline in fasting lipid profile (triglycerides/cholesterol)

End point title	Change from baseline in fasting lipid profile (triglycerides/cholesterol)

End point description:

Between-treatment analysis of change after 24 weeks of treatment and between Week 24 and Week 48

End point type	Secondary

End point timeframe:

Baseline to Week 24, Week 24 to Week 48 (Epoch 4)

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: mmol/L				
arithmetic mean (confidence interval 95%)				
Triglycerides (TG)	-3.8 (-14.91 to 7.26)	1.3 (-11.19 to 13.80)	-11.5 (-24.03 to .093)	-3.0 (-10.94 to 4.91)
Total Cholesterol (TC)	6.0 (-0.92 to 12.99)	7.3 (-0.23 to 14.92)	4.8 (-3.15 to 12.78)	14.6 (9.61 to 19.58)
HDL Cholesterol	0.8 (-5.25 to 6.76)	4.9 (-1.52 to 11.28)	5.2 (-1.55 to 12.01)	8.0 (3.71 to 12.25)
LDL Cholesterol	8.7 (-2.14 to 19.61)	17.5 (5.73 to 29.20)	8.2 (-4.21 to 20.25)	21.8 (14.08 to 29.55)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	38	76
Units: mmol/L				
arithmetic mean (confidence interval 95%)				
Triglycerides (TG)	2.3 (-8.94 to 13.57)	1.7 (-9.30 to 12.77)	5.5 (-5.94 to 16.89)	-7.4 (-15.60 to 0.87)
Total Cholesterol (TC)	1.5 (-5.79 to 8.71)	5.1 (-1.89 to 12.19)	6.4 (-0.94 to 13.75)	8.8 (-0.23 to 9.70)
HDL Cholesterol	2.9 (-3.29 to 9.16)	2.4 (-3.60 to 8.48)	1.5 (-4.86 to 7.81)	8.0 (3.56 to 12.47)
LDL Cholesterol	4.1 (-7.22 to 15.38)	8.7 (-2.26 to 19.68)	7.7 (-3.77 to 19.13)	10.9 (2.80 to 19.04)

End point values	Placebo (Epoch 3)	LIK066 qd/LIK066 25mg qd (Epoch 4)	LIK066 bid/LIK066 35mg qd (Epoch 4)	Placebo/LIK066 25mg qd (Epoch 4)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	158	163	39
Units: mmol/L				
arithmetic mean (confidence interval 95%)				
Triglycerides (TG)	4.0 (-3.82 to 11.87)	6.7 (0.18 to 13.13)	12.4 (5.75 to 19.13)	-0.9 (-14.48 to 12.59)
Total Cholesterol (TC)	4.7 (-0.23 to 9.70)	0.8 (-1.65 to 3.27)	0.3 (-2.22 to 2.81)	0.8 (-4.22 to 5.81)
HDL Cholesterol	0.7 (-3.54 to 5.00)	3.9 (0.84 to 7.03)	3.7 (0.54 to 6.90)	9.2 (2.88 to 15.57)
LDL Cholesterol	12.5 (4.70 to 20.30)	-0.6 (-4.14 to 2.96)	-1.2 (-4.79 to 2.49)	-1.4 (-8.66 to 5.83)

End point values	Placebo/Placebo (Epoch 4)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: mmol/L				
arithmetic mean (confidence interval 95%)				
Triglycerides (TG)	4.8 (-9.57 to 19.16)			
Total Cholesterol (TC)	-1.7 (-7.04 to 3.68)			
HDL Cholesterol	0.7 (-6.11 to 7.48)			
LDL Cholesterol	-3.5 (-11.28 to 4.24)			

Statistical analyses

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.254
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-7.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.37
upper limit	5.65

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.716
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.44
upper limit	11.99

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.038
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-15.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.3
upper limit	-0.86

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.213
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.15
upper limit	4.06

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.806
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.38
upper limit	11.96

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.739
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.8
upper limit	11.21

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.049
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-11.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.71
upper limit	-0.07

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.837
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.36
upper limit	15.26

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.764
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.22
upper limit	9.82

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.571
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.43
upper limit	11.63

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.987
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	9.46

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	9.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.85
upper limit	16.87

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.463
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.03
upper limit	5.48

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.925
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.18
upper limit	9.01

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.711
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.19
upper limit	10.53

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.265
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	11.26

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: HDL Cholesterol	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.995
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.31
upper limit	7.36

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: HDL Cholesterol	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.288
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.52
upper limit	11.81

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: HDL Cholesterol	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.269
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	12.5

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description:	
HDL Cholesterol	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.018
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	13.27

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description:	
HDL Cholesterol	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.565
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.32
upper limit	9.73

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: HDL Cholesterol	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.649
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.67
upper limit	9.09

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: HDL Cholesterol	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.847
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.87
upper limit	8.36

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: HDL Cholesterol	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.02
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.14
upper limit	13.43

Statistical analysis title	LIK066 2.5mg qd vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 2.5mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.579
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.09
upper limit	9.57

Statistical analysis title	LIK066 10mg qd vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 10mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.487
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.08
upper limit	19.02

Statistical analysis title	LIK066 50mg qd vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 50mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.561
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.96
upper limit	10.3

Statistical analysis title	LIK066 150mg qd vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 150mg qd (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.097
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	9.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.68
upper limit	20.25

Statistical analysis title	LIK066 2.5mg bid vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 2.5mg bid (Epoch 3) v Placebo (Epoch 3)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.227
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-8.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.1
upper limit	5.26

Statistical analysis title	LIK066 5mg bid vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 5mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.58
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.22
upper limit	9.64

Statistical analysis title	LIK066 25mg bid vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 25mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.494
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.67
upper limit	9.03

Statistical analysis title	LIK066 50mg bid vs Placebo
Statistical analysis description: LDL Cholesterol	
Comparison groups	LIK066 50mg bid (Epoch 3) v Placebo (Epoch 3)
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.782
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.81
upper limit	9.65

Statistical analysis title	LIK066 qd/LIK066 25mg qd vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 qd/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.816
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.82
upper limit	17.54

Statistical analysis title	LIK066 bid/LIK066 35mg qd vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	LIK066 bid/LIK066 35mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.341
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	8.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.13
upper limit	23.42

Statistical analysis title	Placebo/LIK066 25mg qd vs Placebo
Statistical analysis description: Triglycerides (TG)	
Comparison groups	Placebo/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.566
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	9.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.39
upper limit	13.91

Statistical analysis title	LIK066 qd/LIK066 25mg qd vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 qd/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.405
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	2.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.38
upper limit	8.36

Statistical analysis title	LIK066 bid/LIK066 35mg qd vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	LIK066 bid/LIK066 35mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.511
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.92
upper limit	7.87

Statistical analysis title	Placebo/LIK066 25mg qd vs Placebo
Statistical analysis description: Total Cholesterol (TC)	
Comparison groups	Placebo/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.506
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.83
upper limit	9.79

Statistical analysis title	LIK066 qd/LIK066 25mg qd vs Placebo

Statistical analysis description:	
HDL Cholesterol	
Comparison groups	LIK066 qd/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.392
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	10.7

Statistical analysis title	LIK066 bid/LIK066 35mg qd vs Placebo
Statistical analysis description:	
HDL Cholesterol	
Comparison groups	LIK066 bid/LIK066 35mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.426
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.45
upper limit	10.53

Statistical analysis title	Placebo/LIK066 25mg qd vs Placebo
Statistical analysis description:	
HDL Cholesterol	
Comparison groups	Placebo/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.071
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	8.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.72
upper limit	17.8

Statistical analysis title	LIK066 qd/LIK066 25mg qd vs Placebo
Statistical analysis description:	
LDL Cholesterol	
Comparison groups	LIK066 qd/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.498
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.56
upper limit	11.42

Statistical analysis title	LIK066 bid/LIK066 35mg qd vs Placebo
Statistical analysis description:	
LDL Cholesterol	
Comparison groups	LIK066 bid/LIK066 35mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.586
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.17
upper limit	10.9

Statistical analysis title	Placebo/LIK066 25mg qd vs Placebo

Statistical analysis description:	
LDL Cholesterol	
Comparison groups	Placebo/LIK066 25mg qd (Epoch 4) v Placebo/Placebo (Epoch 4)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.696
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.47
upper limit	12.67

Secondary: Pharmacokinetics of LIK066: Observe maximum plasma concentration (cmax)

End point title	Pharmacokinetics of LIK066: Observe maximum plasma concentration (cmax)[1]

End point description:

Observe maximum plasma concentration following administration of LIK066 (Cmax)

End point type	Secondary

End point timeframe:

Summary at Week 24 from qd or bid regimens

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis done on PK parameters

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: ng/mL				
arithmetic mean (standard deviation)	80.0 (± 97.2)	128 (± 00.0)	798 (± 397)	1810 (± 545)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	37	76
Units: ng/mL				
arithmetic mean (standard deviation)	38.6 (± 5.22)	84.2 (± 19.0)	523 (± 118)	811 (± 367)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of LIK066: Time to reach the maximum concentration (Tmax)

End point title	Pharmacokinetics of LIK066: Time to reach the maximum concentration (Tmax)[2]

End point description:

Time to reach the maximum concentration after administration of LIK066 (Tmax)

End point type	Secondary

End point timeframe:

Summary at Week 24 for qd or bid regimens

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis done on PK parameters

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: hour				
median (full range (min-max))	1.00 (1.00 to 2.00)	1.00 (1.00 to 1.00)	1.01 (1.00 to 2.08)	1.02 (1.00 to 2.00)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	37	76
Units: hour				
median (full range (min-max))	1.00 (0.983 to 1.00)	1.00 (0.917 to 2.00)	0.992 (0.900 to 1.00)	1.00 (0.983 to 2.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of LIK066: Area under the plasma concentration-time curve from time zero time 't' (AUC0-t)

End point title	Pharmacokinetics of LIK066: Area under the plasma concentration-time curve from time zero time 't' (AUC0-t)[3]

End point description:

Area under the plasma concentration-time curve from time zero time 't' where t is a defined time point after administration (AUC0-t)

End point type	Secondary

End point timeframe:

Summary at Week 24 from qd or bid regimens (0-6h)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis done on PK parameters

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: hr*ng/mL				
arithmetic mean (standard deviation)	196 (± 186)	275 (± 000)	2280 (± 522)	5700 (± 1490)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	37	76
Units: hr*ng/mL				
arithmetic mean (standard deviation)	105 (± 17.1)	273 (± 69.3)	1520 (± 277)	2190 (± 841)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of LIK066: Last non-zero concentration area under the curve (AUClast)

End point title	Pharmacokinetics of LIK066: Last non-zero concentration area under the curve (AUClast)[4]

End point description:

Last non-zero concentration area under the curve (AUClast)

End point type	Secondary

End point timeframe:

Summary at Week 24 from qd or bid regimens

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis done on PK parameters

End point values	LIK066 2.5mg qd (Epoch 3)	LIK066 10mg qd (Epoch 3)	LIK066 50mg qd (Epoch 3)	LIK066 150mg qd (Epoch 3)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	38	77
Units: hr*ng/mL				
arithmetic mean (standard deviation)	196 (± 186)	275 (± 000)	2290 (± 526)	5690 (± 1480)

End point values	LIK066 2.5mg bid (Epoch 3)	LIK066 5mg bid (Epoch 3)	LIK066 25mg bid (Epoch 3)	LIK066 50mg bid (Epoch 3)

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	39	37	76
Units: hr*ng/mL				
arithmetic mean (standard deviation)	105 (± 17.2)	273 (± 70.2)	1520 (± 271)	2190 (± 843)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Timeframe for AE	
Adverse event reporting additional description:	
AE additional description	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	LIK066 2.5 mg qd/25 mg qd
Reporting group description:	
LIK066 2.5 mg qd/25 mg qd	
Reporting group title	LIK066 10 mg qd/25 mg qd
Reporting group description:	
LIK066 10 mg qd/25 mg qd	
Reporting group title	LIK066 50 mg qd/25 mg qd
Reporting group description:	
LIK066 50 mg qd/25 mg qd	
Reporting group title	LIK066 150 mg qd/25 mg qd
Reporting group description:	
LIK066 150 mg qd/25 mg qd	
Reporting group title	LIK066 2.5 mg bid/35 mg qd
Reporting group description:	
LIK066 2.5 mg bid/35 mg qd	
Reporting group title	LIK066 5 mg bid/35 mg qd
Reporting group description:	
LIK066 5 mg bid/35 mg qd	
Reporting group title	LIK066 25 mg bid/35 mg qd
Reporting group description:	
LIK066 25 mg bid/35 mg qd	
Reporting group title	LIK066 50 mg bid/35 mg qd
Reporting group description:	
LIK066 50 mg bid/35 mg qd	
Reporting group title	Placebo/LIK066 25 mg qd
Reporting group description:	
Placebo/LIK066 25 mg qd	
Reporting group title	Placebo/Placebo
Reporting group description:	
Placebo/Placebo	

Serious adverse events	LIK066 2.5 mg qd/25 mg qd	LIK066 10 mg qd/25 mg qd	LIK066 50 mg qd/25 mg qd
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 38 (7.89%)	3 / 38 (7.89%)	1 / 38 (2.63%)

number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Leiomyosarcoma			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (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
Uterine leiomyoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Hypertension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (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 disorders			
Acute myocardial infarction			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Angina pectoris			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Atrial fibrillation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Myocardial infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Abdominal pain upper			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Duodenal ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Obstructive pancreatitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Pancreatitis acute			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Dysmenorrhoea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Dyspareunia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Endometrial hyperplasia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (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
Menorrhagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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

Cholecystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Cholecystitis acute			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Cholelithiasis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc disorder			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (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			
Diverticulitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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
Erysipelas			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (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

Serious adverse events	LIK066 150 mg qd/25 mg qd	LIK066 2.5 mg bid/35 mg qd	LIK066 5 mg bid/35 mg qd
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 77 (3.90%)	5 / 38 (13.16%)	2 / 39 (5.13%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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 leiomyoma			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (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
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (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	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Angina pectoris			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Atrial fibrillation			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (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 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Abdominal pain upper			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (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
Duodenal ulcer			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Pancreatitis acute			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Dysmenorrhoea			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Dyspareunia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Endometrial hyperplasia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Menorrhagia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Cholecystitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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

Cholecystitis acute			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (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
Cholelithiasis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (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
Infections and infestations			
Diverticulitis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (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	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (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

Serious adverse events	LIK066 25 mg bid/35 mg qd	LIK066 50 mg bid/35 mg qd	Placebo/LIK066 25 mg qd
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 38 (5.26%)	1 / 76 (1.32%)	1 / 40 (2.50%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Leiomyosarcoma			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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 leiomyoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Hypertension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Atrial fibrillation			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Myocardial infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (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
Abdominal pain upper			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Duodenal ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Pancreatitis acute			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Reproductive system and breast			

disorders			
Breast enlargement			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (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
Dysmenorrhoea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Dyspareunia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Endometrial hyperplasia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Menorrhagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Cholecystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Cholecystitis acute			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (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

Cholelithiasis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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
Erysipelas			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (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

Serious adverse events	Placebo/Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 38 (10.53%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leiomyosarcoma			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			

subjects affected / exposed	1 / 38 (2.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 38 (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 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			

subjects affected / exposed	0 / 38 (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 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructive pancreatitis			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Dysmenorrhoea				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dyspareunia				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endometrial hyperplasia				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Menorrhagia				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct stone				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue				

disorders			
Intervertebral disc disorder			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	0 / 38 (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: 2 %

Non-serious adverse events	LIK066 2.5 mg qd/25 mg qd	LIK066 10 mg qd/25 mg qd	LIK066 50 mg qd/25 mg qd
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 38 (86.84%)	24 / 38 (63.16%)	24 / 38 (63.16%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm of conjunctiva			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Neuroma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Papilloma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Hot flush			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Hypotension			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Peripheral venous disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Shock haemorrhagic			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Unintended pregnancy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Feeling cold			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hunger			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Thirst			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0

Reproductive system and breast disorders			
Atrophic vulvovaginitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Breast haematoma			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Endometrial hyperplasia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Epididymal cyst			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Menopausal symptoms			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Menorrhagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Menstrual disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			

subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Vulval disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hydrothorax			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Pleuritic pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Respiratory tract congestion			

subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Sneezing			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	2 / 38 (5.26%)
occurrences (all)	1	0	2
Binge drinking			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 38 (2.63%)	2 / 38 (5.26%)	1 / 38 (2.63%)
occurrences (all)	1	2	1
Grief reaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	2 / 38 (5.26%)
occurrences (all)	1	1	2

Organic brain syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Schizophrenia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Apolipoprotein A-I decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Blood albumin increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			

subjects affected / exposed	2 / 38 (5.26%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Blood glucose increased			
subjects affected / exposed	2 / 38 (5.26%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Blood magnesium decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Blood uric acid increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Creatinine urine increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram change			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 38 (5.26%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	2	1	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Haematocrit increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Haemoglobin increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Haemoglobin urine present			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Heart rate decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
High density lipoprotein decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Lipase abnormal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Liver scan abnormal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Protein urine present			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Serum ferritin decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	2 / 38 (5.26%)	1 / 38 (2.63%)	3 / 38 (7.89%)
occurrences (all)	2	1	4
Urine leukocyte esterase			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Anastomotic ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Epicondylitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Laceration			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Ligament rupture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	3 / 38 (7.89%)
occurrences (all)	1	0	3
Limb injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 38 (0.00%)	2 / 38 (5.26%)	1 / 38 (2.63%)
occurrences (all)	0	2	1
Post procedural complication			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Porokeratosis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Type IIa hyperlipidaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Bundle branch block right			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Microvascular coronary artery disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Carpal tunnel syndrome			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Dizziness postural			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 38 (5.26%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	3	2	0
Hypoaesthesia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Hyposmia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Nerve compression			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 38 (2.63%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	1	2	0
Sinus headache			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Syncope			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Polycythaemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eustachian tube dysfunction			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Inner ear disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Tympanic membrane perforation			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vertigo positional			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eye movement disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Myopic chorioretinal degeneration			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Ulcerative keratitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Vitreous floaters			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	3 / 38 (7.89%)
occurrences (all)	3	1	4
Abdominal distension			
subjects affected / exposed	3 / 38 (7.89%)	2 / 38 (5.26%)	4 / 38 (10.53%)
occurrences (all)	5	4	5
Abdominal pain			
subjects affected / exposed	2 / 38 (5.26%)	1 / 38 (2.63%)	2 / 38 (5.26%)
occurrences (all)	3	2	2
Abdominal pain lower			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 38 (5.26%)	3 / 38 (7.89%)	4 / 38 (10.53%)
occurrences (all)	6	3	6
Bowel movement irregularity			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Breath odour			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Change of bowel habit			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Chronic gastritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	6 / 38 (15.79%)	7 / 38 (18.42%)	6 / 38 (15.79%)
occurrences (all)	7	9	6
Defaecation urgency			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	4 / 38 (10.53%)
occurrences (all)	0	0	4
Diarrhoea			

subjects affected / exposed	14 / 38 (36.84%)	7 / 38 (18.42%)	15 / 38 (39.47%)
occurrences (all)	14	12	23
Diverticulum			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Dyschezia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	3 / 38 (7.89%)	1 / 38 (2.63%)	1 / 38 (2.63%)
occurrences (all)	3	1	1
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	2 / 38 (5.26%)
occurrences (all)	3	1	3
Faeces hard			
subjects affected / exposed	2 / 38 (5.26%)	2 / 38 (5.26%)	2 / 38 (5.26%)
occurrences (all)	3	2	2
Flatulence			
subjects affected / exposed	7 / 38 (18.42%)	9 / 38 (23.68%)	9 / 38 (23.68%)
occurrences (all)	11	11	11
Frequent bowel movements			
subjects affected / exposed	2 / 38 (5.26%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	2	1	0
Gastritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal motility disorder			
subjects affected / exposed	2 / 38 (5.26%)	2 / 38 (5.26%)	4 / 38 (10.53%)
occurrences (all)	4	2	4
Gastrointestinal pain			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	4 / 38 (10.53%)
occurrences (all)	3	1	5
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 38 (2.63%)	3 / 38 (7.89%)	3 / 38 (7.89%)
occurrences (all)	1	3	4
Splenic artery aneurysm			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 38 (7.89%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	5	0	1
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Lichen sclerosus			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 38 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Pustular psoriasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Rash maculo-papular			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Lower urinary tract symptoms			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Pollakiuria			

subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Renal cyst			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	2	1	0
Arthritis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	3 / 38 (7.89%)	4 / 38 (10.53%)	1 / 38 (2.63%)
occurrences (all)	3	5	1
Bursitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Dupuytren's contracture			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Extremity contracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fibromyalgia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Joint effusion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Musculoskeletal pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	2 / 38 (5.26%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	2	3	0
Pain in extremity			
subjects affected / exposed	3 / 38 (7.89%)	3 / 38 (7.89%)	1 / 38 (2.63%)
occurrences (all)	3	3	1
Pain in jaw			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Scleroderma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Spinal osteoarthritis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Tendon pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Tendonitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Tenosynovitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Acute sinusitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Bacterial vulvovaginitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Balanitis candida			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	4 / 38 (10.53%)	0 / 38 (0.00%)	2 / 38 (5.26%)
occurrences (all)	4	0	2
Cellulitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Cystitis bacterial			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Epiglottitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0

Fungal infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Genital candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Genital herpes zoster			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Genital infection fungal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 38 (5.26%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0

Nasopharyngitis			
subjects affected / exposed	4 / 38 (10.53%)	2 / 38 (5.26%)	3 / 38 (7.89%)
occurrences (all)	5	2	3
Onychomycosis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Oral herpes			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Otitis externa fungal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0

Pulpitis dental			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Sinobronchitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	3 / 38 (7.89%)
occurrences (all)	1	1	3
Tinea pedis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Tooth abscess			
subjects affected / exposed	2 / 38 (5.26%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Tooth infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Tracheitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 38 (5.26%)	3 / 38 (7.89%)	3 / 38 (7.89%)
occurrences (all)	3	6	5
Urinary tract infection			
subjects affected / exposed	3 / 38 (7.89%)	1 / 38 (2.63%)	3 / 38 (7.89%)
occurrences (all)	5	2	3
Urinary tract infection bacterial			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1

Vaginal infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vestibular neuronitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 38 (5.26%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	2	2	0
Vulvitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Wound infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Diabetes mellitus			

subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Gout			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Hyperglycaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	9	0	3
Hyperkalaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Hyperlipidaemia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Hypoglycaemia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	4	1	0
Hypokalaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Increased appetite			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	1 / 38 (2.63%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Ketosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Polydipsia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 38 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	LIK066 150 mg qd/25 mg qd	LIK066 2.5 mg bid/35 mg qd	LIK066 5 mg bid/35 mg qd
Total subjects affected by non-serious adverse events			
subjects affected / exposed	55 / 77 (71.43%)	31 / 38 (81.58%)	32 / 39 (82.05%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm of conjunctiva			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Neuroma			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Papilloma			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hypotension			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Peripheral arterial occlusive disease			

subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Peripheral venous disease			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Shock haemorrhagic			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Thrombophlebitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Unintended pregnancy			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Feeling cold			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Hunger			

subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Thirst			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Atrophic vulvovaginitis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Balanoposthitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	2
Breast haematoma			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Endometrial hyperplasia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Epididymal cyst			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Menopausal symptoms			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Menorrhagia			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Menstrual disorder			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Metrorrhagia			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Prostatomegaly			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Vaginal discharge			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vulval disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Vulvovaginal pruritus			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			

disorders			
Cough			
subjects affected / exposed	4 / 77 (5.19%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	4	0	1
Dysphonia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hydrothorax			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Pleuritic pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Sleep apnoea syndrome			

subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Sneezing			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 77 (3.90%)	1 / 38 (2.63%)	1 / 39 (2.56%)
occurrences (all)	3	1	1
Binge drinking			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Grief reaction			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Organic brain syndrome			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Schizophrenia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0

Product issues			
Device dislocation			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Cholelithiasis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hepatic steatosis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Investigations			
Amylase decreased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Apolipoprotein A-I decreased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood albumin increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Blood glucose increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			

subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Blood potassium increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Creatinine urine increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram change			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Glomerular filtration rate increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haematocrit increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haemoglobin increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Haemoglobin urine present			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Heart rate irregular			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
High density lipoprotein decreased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Lipase abnormal			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Liver scan abnormal			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			

subjects affected / exposed	1 / 77 (1.30%)	5 / 38 (13.16%)	1 / 39 (2.56%)
occurrences (all)	1	7	1
Urine leukocyte esterase			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Anastomotic ulcer			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Animal bite			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Ankle fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	2	0
Fall			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Foot fracture			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	4 / 77 (5.19%)	2 / 38 (5.26%)	0 / 39 (0.00%)
occurrences (all)	4	2	0
Limb injury			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Muscle rupture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Post procedural complication			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Post procedural discomfort			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Post-traumatic pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Porokeratosis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Type IIa hyperlipidaemia			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Microvascular coronary artery disease			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Dizziness postural			

subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Facial paralysis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	3 / 39 (7.69%)
occurrences (all)	2	0	3
Hypoaesthesia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Hyposmia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Nerve compression			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Sinus headache			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Polycythaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eustachian tube dysfunction			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Inner ear disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Vertigo positional			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	1 / 77 (1.30%)	2 / 38 (5.26%)	0 / 39 (0.00%)
occurrences (all)	1	2	0
Dry eye			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eye movement disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Myopic chorioretinal degeneration			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ulcerative keratitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	7 / 77 (9.09%)	3 / 38 (7.89%)	3 / 39 (7.69%)
occurrences (all)	7	3	6
Abdominal distension			

subjects affected / exposed	8 / 77 (10.39%)	9 / 38 (23.68%)	5 / 39 (12.82%)
occurrences (all)	9	10	5
Abdominal pain			
subjects affected / exposed	3 / 77 (3.90%)	1 / 38 (2.63%)	3 / 39 (7.69%)
occurrences (all)	4	1	3
Abdominal pain lower			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	7 / 77 (9.09%)	7 / 38 (18.42%)	3 / 39 (7.69%)
occurrences (all)	12	9	3
Bowel movement irregularity			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Breath odour			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Change of bowel habit			
subjects affected / exposed	3 / 77 (3.90%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	3	0	0
Chronic gastritis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	11 / 77 (14.29%)	12 / 38 (31.58%)	5 / 39 (12.82%)
occurrences (all)	12	14	5
Defaecation urgency			
subjects affected / exposed	7 / 77 (9.09%)	5 / 38 (13.16%)	1 / 39 (2.56%)
occurrences (all)	11	6	1
Diarrhoea			
subjects affected / exposed	42 / 77 (54.55%)	16 / 38 (42.11%)	12 / 39 (30.77%)
occurrences (all)	64	23	19
Diverticulum			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dry mouth			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	1 / 77 (1.30%)	10 / 38 (26.32%)	5 / 39 (12.82%)
occurrences (all)	2	14	9
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Eructation			
subjects affected / exposed	5 / 77 (6.49%)	5 / 38 (13.16%)	1 / 39 (2.56%)
occurrences (all)	5	5	1
Faeces hard			
subjects affected / exposed	3 / 77 (3.90%)	5 / 38 (13.16%)	0 / 39 (0.00%)
occurrences (all)	3	6	0
Flatulence			
subjects affected / exposed	21 / 77 (27.27%)	12 / 38 (31.58%)	6 / 39 (15.38%)
occurrences (all)	27	20	9
Frequent bowel movements			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal motility disorder			
subjects affected / exposed	3 / 77 (3.90%)	7 / 38 (18.42%)	0 / 39 (0.00%)
occurrences (all)	3	9	0
Gastrointestinal pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	5 / 77 (6.49%)	4 / 38 (10.53%)	1 / 39 (2.56%)
occurrences (all)	6	5	1
Gastrooesophageal reflux disease			

subjects affected / exposed	3 / 77 (3.90%)	2 / 38 (5.26%)	3 / 39 (7.69%)
occurrences (all)	3	2	3
Glossodynia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Large intestine polyp			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 77 (3.90%)	8 / 38 (21.05%)	3 / 39 (7.69%)
occurrences (all)	6	10	3
Splenic artery aneurysm			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Vomiting			

subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Hyperkeratosis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Lichen sclerosus			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pustular psoriasis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	2
Rosacea			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1

Skin fissures			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Dysuria			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Haematuria			
subjects affected / exposed	2 / 77 (2.60%)	1 / 38 (2.63%)	2 / 39 (5.13%)
occurrences (all)	2	1	2
Hypertonic bladder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Lower urinary tract symptoms			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Microalbuminuria			
subjects affected / exposed	1 / 77 (1.30%)	3 / 38 (7.89%)	0 / 39 (0.00%)
occurrences (all)	1	3	0
Pollakiuria			
subjects affected / exposed	0 / 77 (0.00%)	2 / 38 (5.26%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Proteinuria			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Renal cyst			

subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Renal impairment			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 77 (7.79%)	2 / 38 (5.26%)	2 / 39 (5.13%)
occurrences (all)	6	3	3
Arthritis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	7 / 77 (9.09%)	2 / 38 (5.26%)	4 / 39 (10.26%)
occurrences (all)	9	2	4
Bursitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dupuytren's contracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Extremity contracture			

subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Fibromyalgia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Joint effusion			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 77 (0.00%)	2 / 38 (5.26%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	3 / 77 (3.90%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	3	1	0
Pain in extremity			

subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Pain in jaw			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Scleroderma			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Bacterial vulvovaginitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Balanitis candida			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Cellulitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Cystitis bacterial			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Epiglottitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	3
Eye infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1

Gastroenteritis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Gastroenteritis viral			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Gastrointestinal viral infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Genital herpes zoster			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	2 / 77 (2.60%)	1 / 38 (2.63%)	2 / 39 (5.13%)
occurrences (all)	2	2	2
Helicobacter infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	3 / 77 (3.90%)	5 / 38 (13.16%)	2 / 39 (5.13%)
occurrences (all)	4	6	2
Nasopharyngitis			
subjects affected / exposed	8 / 77 (10.39%)	4 / 38 (10.53%)	3 / 39 (7.69%)
occurrences (all)	9	6	4
Onychomycosis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Oral candidiasis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Otitis externa			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Otitis externa fungal			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Post procedural infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	3 / 77 (3.90%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	3	0	0

Sinobronchitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Tinea pedis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	7 / 77 (9.09%)	2 / 38 (5.26%)	2 / 39 (5.13%)
occurrences (all)	8	2	3
Urinary tract infection			
subjects affected / exposed	1 / 77 (1.30%)	1 / 38 (2.63%)	4 / 39 (10.26%)
occurrences (all)	1	1	4
Urinary tract infection bacterial			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Vestibular neuronitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Viral infection			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 77 (2.60%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Vulvitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Wound infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	1 / 77 (1.30%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	2 / 77 (2.60%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Hypoglycaemia			
subjects affected / exposed	3 / 77 (3.90%)	4 / 38 (10.53%)	2 / 39 (5.13%)
occurrences (all)	3	10	28
Hypokalaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ketosis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 77 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			

subjects affected / exposed	0 / 77 (0.00%)	1 / 38 (2.63%)	0 / 39 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	LIK066 25 mg bid/35 mg qd	LIK066 50 mg bid/35 mg qd	Placebo/LIK066 25 mg qd
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 38 (68.42%)	47 / 76 (61.84%)	32 / 40 (80.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Benign neoplasm of conjunctiva			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Neuroma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Papilloma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Hypertension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Peripheral venous disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Shock haemorrhagic			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Pregnancy, puerperium and perinatal conditions			
Unintended pregnancy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Feeling cold			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hunger			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Oedema peripheral			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	2
Peripheral swelling			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
Atrophic vulvovaginitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Balanoposthitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Breast haematoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Endometrial hyperplasia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Epididymal cyst			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Menopausal symptoms			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Menorrhagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Menstrual disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vulval disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	2 / 38 (5.26%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 38 (2.63%)	2 / 76 (2.63%)	0 / 40 (0.00%)
occurrences (all)	1	2	0
Dysphonia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Hydrothorax			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	2 / 38 (5.26%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Pleuritic pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Sleep apnoea syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Upper respiratory tract congestion			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	2
Upper-airway cough syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	2 / 40 (5.00%)
occurrences (all)	1	1	2
Binge drinking			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	2 / 38 (5.26%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Grief reaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Organic brain syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Schizophrenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

Biliary dyskinesia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Investigations			
Amylase decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Apolipoprotein A-I decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood albumin increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 38 (2.63%)	3 / 76 (3.95%)	0 / 40 (0.00%)
occurrences (all)	1	5	0
Blood glucose increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	2
Blood uric acid increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Creatinine urine increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram change			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haematocrit increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haemoglobin increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haemoglobin urine present			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Heart rate decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
High density lipoprotein decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lipase abnormal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Liver scan abnormal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Urine leukocyte esterase			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	2	0	2
Weight increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Anastomotic ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Epicondylitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hand fracture			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Joint injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Limb injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Post procedural complication			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Porokeratosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Type IIa hyperlipidaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Microvascular coronary artery disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Dizziness			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Dizziness postural			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Facial paralysis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Hypoaesthesia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hyposmia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Nerve compression			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Tremor			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1

Iron deficiency anaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Polycythaemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eustachian tube dysfunction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Inner ear disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Vertigo positional			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Blepharospasm			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Eye movement disorder			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Myopic chorioretinal degeneration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ulcerative keratitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	4 / 38 (10.53%)	6 / 76 (7.89%)	6 / 40 (15.00%)
occurrences (all)	6	9	7
Abdominal pain			

subjects affected / exposed	2 / 38 (5.26%)	2 / 76 (2.63%)	1 / 40 (2.50%)
occurrences (all)	2	2	1
Abdominal pain lower			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	4 / 38 (10.53%)	4 / 76 (5.26%)	4 / 40 (10.00%)
occurrences (all)	10	10	4
Bowel movement irregularity			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Breath odour			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Change of bowel habit			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	8 / 38 (21.05%)	8 / 76 (10.53%)	7 / 40 (17.50%)
occurrences (all)	11	8	9
Defaecation urgency			
subjects affected / exposed	4 / 38 (10.53%)	3 / 76 (3.95%)	1 / 40 (2.50%)
occurrences (all)	6	3	2
Diarrhoea			
subjects affected / exposed	14 / 38 (36.84%)	29 / 76 (38.16%)	14 / 40 (35.00%)
occurrences (all)	28	50	18
Diverticulum			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Dyschezia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	4 / 38 (10.53%)	6 / 76 (7.89%)	3 / 40 (7.50%)
occurrences (all)	6	9	3
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	3 / 38 (7.89%)	4 / 76 (5.26%)	2 / 40 (5.00%)
occurrences (all)	3	6	2
Faeces hard			
subjects affected / exposed	2 / 38 (5.26%)	2 / 76 (2.63%)	1 / 40 (2.50%)
occurrences (all)	5	2	1
Flatulence			
subjects affected / exposed	11 / 38 (28.95%)	21 / 76 (27.63%)	6 / 40 (15.00%)
occurrences (all)	15	24	6
Frequent bowel movements			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal motility disorder			
subjects affected / exposed	3 / 38 (7.89%)	2 / 76 (2.63%)	0 / 40 (0.00%)
occurrences (all)	5	3	0
Gastrointestinal pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	4 / 38 (10.53%)	3 / 76 (3.95%)	1 / 40 (2.50%)
occurrences (all)	7	5	2
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 38 (2.63%)	4 / 76 (5.26%)	1 / 40 (2.50%)
occurrences (all)	2	6	1
Glossodynia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Melaena			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 38 (7.89%)	4 / 76 (5.26%)	5 / 40 (12.50%)
occurrences (all)	4	4	6
Splenic artery aneurysm			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 38 (0.00%)	3 / 76 (3.95%)	0 / 40 (0.00%)
occurrences (all)	0	3	0
Vomiting			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			

Dermal cyst			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	3
Lichen sclerosus			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pustular psoriasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 38 (0.00%)	2 / 76 (2.63%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Rash maculo-papular			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Skin ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Haematuria			
subjects affected / exposed	2 / 38 (5.26%)	0 / 76 (0.00%)	3 / 40 (7.50%)
occurrences (all)	2	0	4
Hypertonic bladder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Renal cyst			
subjects affected / exposed	0 / 38 (0.00%)	2 / 76 (2.63%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Renal impairment			

subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 38 (5.26%)	2 / 76 (2.63%)	2 / 40 (5.00%)
occurrences (all)	2	2	3
Arthritis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	3 / 38 (7.89%)	5 / 76 (6.58%)	3 / 40 (7.50%)
occurrences (all)	5	5	3
Bursitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Costochondritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Dupuytren's contracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Exostosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Extremity contracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Fibromyalgia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Joint effusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	2 / 40 (5.00%)
occurrences (all)	1	1	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Pain in extremity			
subjects affected / exposed	1 / 38 (2.63%)	3 / 76 (3.95%)	0 / 40 (0.00%)
occurrences (all)	1	3	0
Pain in jaw			

subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Plantar fasciitis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Scleroderma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Spinal pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	2
Tenosynovitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Trigger finger			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Bacterial vulvovaginitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Balanitis candida			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1

Bronchitis			
subjects affected / exposed	2 / 38 (5.26%)	2 / 76 (2.63%)	3 / 40 (7.50%)
occurrences (all)	2	3	3
Cellulitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cystitis bacterial			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Ear infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Epiglottitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Escherichia urinary tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2

Gastroenteritis viral			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Gastrointestinal viral infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Genital herpes zoster			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Helicobacter infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 38 (5.26%)	3 / 76 (3.95%)	1 / 40 (2.50%)
occurrences (all)	2	4	1
Nasopharyngitis			
subjects affected / exposed	7 / 38 (18.42%)	5 / 76 (6.58%)	0 / 40 (0.00%)
occurrences (all)	9	6	0
Onychomycosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Otitis externa fungal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Sinobronchitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	1 / 38 (2.63%)	3 / 76 (3.95%)	3 / 40 (7.50%)
occurrences (all)	1	3	3
Tinea pedis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	2 / 76 (2.63%)	5 / 40 (12.50%)
occurrences (all)	3	2	7
Urinary tract infection			
subjects affected / exposed	4 / 38 (10.53%)	4 / 76 (5.26%)	2 / 40 (5.00%)
occurrences (all)	6	5	2
Urinary tract infection bacterial			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Vestibular neuronitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Viral upper respiratory tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vulvitis			
subjects affected / exposed	0 / 38 (0.00%)	2 / 76 (2.63%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 38 (2.63%)	3 / 76 (3.95%)	1 / 40 (2.50%)
occurrences (all)	1	3	1
Wound infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Dehydration			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 38 (0.00%)	1 / 76 (1.32%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 38 (0.00%)	2 / 76 (2.63%)	0 / 40 (0.00%)
occurrences (all)	0	6	0
Hyperkalaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Hypoglycaemia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 76 (1.32%)	1 / 40 (2.50%)
occurrences (all)	1	1	2
Hypokalaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ketosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 38 (2.63%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 38 (0.00%)	0 / 76 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo/Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 38 (84.21%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Benign neoplasm of conjunctiva			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Neuroma			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Papilloma			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	3 / 38 (7.89%)		
occurrences (all)	3		
Hypotension			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Peripheral venous disease			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Shock haemorrhagic			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Thrombophlebitis			

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Unintended pregnancy			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	2 / 38 (5.26%)		
occurrences (all)	2		
Feeling cold			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hunger			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Pain			

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Thirst			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Atrophic vulvovaginitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Balanoposthitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Breast haematoma			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Endometrial hyperplasia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Epididymal cyst			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Menopausal symptoms			

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Menorrhagia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Menstrual disorder			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Metrorrhagia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Prostatomegaly			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Scrotal oedema			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vaginal discharge			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vulval disorder			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vulvovaginal pruritus			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 38 (7.89%)		
occurrences (all)	3		
Dysphonia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Dyspnoea			

subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Epistaxis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Hydrothorax				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Nasal congestion				
subjects affected / exposed	2 / 38 (5.26%)			
occurrences (all)	2			
Oropharyngeal pain				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Pleuritic pain				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Respiratory tract congestion				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Rhinitis allergic				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Sinus congestion				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Sleep apnoea syndrome				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Sneezing				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Upper respiratory tract congestion				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Upper-airway cough syndrome				

subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Binge drinking subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all) Grief reaction subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all) Organic brain syndrome subjects affected / exposed occurrences (all) Schizophrenia subjects affected / exposed occurrences (all) Stress subjects affected / exposed occurrences (all)	 2 / 38 (5.26%) 2 0 / 38 (0.00%) 0 2 / 38 (5.26%) 2 0 / 38 (0.00%) 0 0 / 38 (0.00%) 0 0 / 38 (0.00%) 0 0 / 38 (0.00%) 0 0 / 38 (0.00%) 0		
Product issues Device dislocation subjects affected / exposed occurrences (all)	 0 / 38 (0.00%) 0		
Hepatobiliary disorders Biliary dyskinesia subjects affected / exposed occurrences (all) Cholelithiasis	 0 / 38 (0.00%) 0		

subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Hepatic steatosis			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Investigations			
Amylase decreased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Apolipoprotein A-I decreased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood albumin increased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood glucose increased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood magnesium decreased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood potassium decreased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood potassium increased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood uric acid increased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		

Cardiac murmur				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Creatinine urine increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Electrocardiogram change				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Glomerular filtration rate decreased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Glomerular filtration rate increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Glycosylated haemoglobin increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Haematocrit increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Haemoglobin increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Haemoglobin urine present				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Heart rate decreased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Heart rate irregular				

subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
High density lipoprotein decreased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Lipase abnormal				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Lipase increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Liver function test increased				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Liver scan abnormal				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Prostatic specific antigen increased				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Protein urine present				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Serum ferritin decreased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Urine albumin/creatinine ratio increased				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Urine leukocyte esterase				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Urine leukocyte esterase positive				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			

Weight increased			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Anastomotic ulcer			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Animal bite			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Ankle fracture			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Epicondylitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Foot fracture			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Hand fracture			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Joint injury			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Laceration			

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Ligament rupture			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Ligament sprain			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Limb injury			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Muscle rupture			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Post procedural complication			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Post procedural discomfort			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Post-traumatic pain			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic			

disorders			
Porokeratosis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Type IIa hyperlipidaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Bundle branch block right			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Microvascular coronary artery disease			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Sinus tachycardia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Dizziness postural			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Facial paralysis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	4		

Hypoaesthesia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hyposmia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Nerve compression			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Sciatica			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Sinus headache			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Neutropenia			

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Polycythaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Thrombocytosis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Eustachian tube dysfunction			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Inner ear disorder			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Vertigo positional			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Cataract			

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Eye movement disorder			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Eye pruritus			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Myopic chorioretinal degeneration			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Ulcerative keratitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vitreous floaters			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	4 / 38 (10.53%)		
occurrences (all)	5		
Abdominal distension			
subjects affected / exposed	7 / 38 (18.42%)		
occurrences (all)	8		
Abdominal pain			
subjects affected / exposed	4 / 38 (10.53%)		
occurrences (all)	5		
Abdominal pain lower			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		

Abdominal pain upper				
subjects affected / exposed	4 / 38 (10.53%)			
occurrences (all)	6			
Bowel movement irregularity				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Breath odour				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Change of bowel habit				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Chronic gastritis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	9 / 38 (23.68%)			
occurrences (all)	15			
Defaecation urgency				
subjects affected / exposed	3 / 38 (7.89%)			
occurrences (all)	4			
Diarrhoea				
subjects affected / exposed	8 / 38 (21.05%)			
occurrences (all)	17			
Diverticulum				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Dry mouth				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Dyschezia				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	10 / 38 (26.32%)			
occurrences (all)	10			

Eosinophilic oesophagitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Eructation				
subjects affected / exposed	2 / 38 (5.26%)			
occurrences (all)	4			
Faeces hard				
subjects affected / exposed	3 / 38 (7.89%)			
occurrences (all)	5			
Flatulence				
subjects affected / exposed	8 / 38 (21.05%)			
occurrences (all)	9			
Frequent bowel movements				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Gastrointestinal motility disorder				
subjects affected / exposed	4 / 38 (10.53%)			
occurrences (all)	7			
Gastrointestinal pain				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Gastrointestinal sounds abnormal				
subjects affected / exposed	3 / 38 (7.89%)			
occurrences (all)	5			
Gastrooesophageal reflux disease				
subjects affected / exposed	3 / 38 (7.89%)			
occurrences (all)	5			
Glossodynia				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			

Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Irritable bowel syndrome			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Large intestine polyp			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Melaena			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	5 / 38 (13.16%)		
occurrences (all)	6		
Splenic artery aneurysm			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Tooth disorder			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			

subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Dermatitis contact				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Eczema				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Hyperkeratosis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Lichen sclerosus				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Pustular psoriasis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Rosacea				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Skin fissures				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Skin ulcer				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Urticaria				

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Hypertonic bladder			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Lower urinary tract symptoms			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Microalbuminuria			
subjects affected / exposed	3 / 38 (7.89%)		
occurrences (all)	3		
Pollakiuria			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Proteinuria			
subjects affected / exposed	3 / 38 (7.89%)		
occurrences (all)	3		
Renal cyst			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Renal impairment			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 38 (5.26%)		
occurrences (all)	5		
Arthritis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Bursitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Costochondritis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Dupuytren's contracture			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Exostosis			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Extremity contracture			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Fibromyalgia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Intervertebral disc protrusion			

subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Joint effusion				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Joint swelling				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Muscle spasms				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Musculoskeletal pain				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Neck pain				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Osteoarthritis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Pain in extremity				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Pain in jaw				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Plantar fasciitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Scleroderma				

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Spinal osteoarthritis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Tendon pain			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Tenosynovitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Trigger finger			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Bacterial vulvovaginitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Balanitis candida			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	2 / 38 (5.26%)		
occurrences (all)	2		
Cellulitis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		

Cystitis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Cystitis bacterial				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Epiglottitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Eye infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Fungal infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Fungal skin infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Gastroenteritis viral				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Gastrointestinal viral infection				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			

Genital candidiasis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Genital herpes zoster				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Genital infection fungal				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Helicobacter infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Herpes simplex				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Hordeolum				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	2 / 38 (5.26%)			
occurrences (all)	2			
Nasopharyngitis				
subjects affected / exposed	2 / 38 (5.26%)			
occurrences (all)	3			
Onychomycosis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			

Otitis externa fungal				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Pharyngitis streptococcal				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Post procedural infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Pulpitis dental				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Sinobronchitis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Sinusitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Tinea pedis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			

Tonsillitis				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Tooth abscess				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Tooth infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	5 / 38 (13.16%)			
occurrences (all)	6			
Urinary tract infection				
subjects affected / exposed	5 / 38 (13.16%)			
occurrences (all)	5			
Urinary tract infection bacterial				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Vaginal infection				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Vestibular neuronitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	3 / 38 (7.89%)			
occurrences (all)	5			
Viral upper respiratory tract infection				
subjects affected / exposed	1 / 38 (2.63%)			
occurrences (all)	1			
Vulvitis				
subjects affected / exposed	0 / 38 (0.00%)			
occurrences (all)	0			

Vulvovaginal candidiasis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Wound infection			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		
Diabetes mellitus			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	2 / 38 (5.26%)		
occurrences (all)	3		
Hypercholesterolaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hyperlipidaemia			

subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	2 / 38 (5.26%)		
occurrences (all)	11		
Hypokalaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Increased appetite			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Iron deficiency			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Ketosis			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Polydipsia			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 38 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	1 / 38 (2.63%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 September 2017	The protocol was amended to provide information related to a new risk recently identified from data of the SGLT-2 inhibitor canagliflozin where more cases of lower limb amputations (mainly of the toe) have been observed in the canagliflozin group compared to the placebo group. No lower limb amputations were seen in LIK066 studies, but this risk may constitute a possible class-effect. Patients with a history of lower limb amputation were excluded from enrollment into the study. As a precautionary measure, patients with any history of ketoacidosis, lactic acidosis, or hyperosmolar coma were excluded from enrollment into the study as well. Furthermore, some minor changes and corrections of inconsistencies and typographical errors have been done.This amendment was not considered to have affected the interpretation of study results.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported