Clinical trial results:
Randomized Controlled Trial of Lasmiditan Over Four Migraine Attacks

Summary

EudraCT number	2018-001661-17
Trial protocol	GB NL DE DK CZ ES AT HU IT
Global end of trial date	08 July 2021

Results information

Result version number	v2 (current)
This version publication date	15 July 2022
First version publication date	28 June 2021
Version creation reason	• New data added to full data set New data added to full data set

Trial information

Trial identification

Sponsor protocol code	H8H-MC-LAIJ

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03670810
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17131

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 July 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To evaluate the efficacy of lasmiditan 200 mg and 100 mg on migraine headache pain freedom compared to placebo.
- To evaluate the consistency of response to lasmiditan 200 mg and 100 mg compared to placebo.

Main objective of the Open-Label Extension was to evaluate the effect of Lasmiditan on migraine related disability (MIDAS Total Score).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 June 2019
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	China: 281
Country: Number of subjects enrolled	India: 47
Country: Number of subjects enrolled	Mexico: 95
Country: Number of subjects enrolled	Russian Federation: 47
Country: Number of subjects enrolled	United States: 82
Country: Number of subjects enrolled	Austria: 11
Country: Number of subjects enrolled	Belgium: 28
Country: Number of subjects enrolled	Denmark: 30
Country: Number of subjects enrolled	France: 22
Country: Number of subjects enrolled	Germany: 275
Country: Number of subjects enrolled	Hungary: 17
Country: Number of subjects enrolled	Italy: 22
Country: Number of subjects enrolled	Netherlands: 10
Country: Number of subjects enrolled	Spain: 61
Country: Number of subjects enrolled	Switzerland: 19
Country: Number of subjects enrolled	Czechia: 96

Country: Number of subjects enrolled	United Kingdom: 490
Worldwide total number of subjects	1633
EEA total number of subjects	572

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)	1592
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were considered study completers after treating 4 migraine attacks or after completing 4 months of study duration regardless of number of treated attacks in the main study. Participants may continue in Open-Label Extension (OLE) if they met OLE eligibility criteria.

Pre-assignment

Screening details:

An ITT evaluable attack is defined as a treated attack of least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	100 mg Lasmiditan

Arm description:

Participants received one 100 mg Lasmiditan tablet with one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 100 mg Lasmiditan tablet administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm title	200 mg Lasmiditan

Arm description:

Participants received two 100 mg Lasmiditan tablets with one 50 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental

Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received two 100 mg Lasmiditan tablets administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 50 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm title	Control 1 Sequence

Arm description:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 4.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind, for migraine attack 3.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 50 mg Lasmiditan tablet administered orally to treat migraine attack 3. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received two 100 mg Lasmiditan matching placebo tablet to maintain blind for migraine attacks 1, 2 and 4. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm title	Control 2 Sequence

Arm description:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 3.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attack 4.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental

Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 50 mg Lasmiditan tablet administer orally to treat migraine attack 4. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received two 100 mg Lasmiditan matching placebo tablet to maintain blind for migraine attacks 1, 2, and 3. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm title	100 mg Lasmiditan Maximum Extended Enrollment (MEE)

Arm description:

Participants received one 100 mg Lasmiditan tablet with one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 100 mg Lasmiditan tablet with one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm title	200 mg Lasmiditan MEE

Arm description:

Participants received two 100 mg Lasmiditan tablets with one 50 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received two 100 mg Lasmiditan tablets with one 50 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm title	Control 1 Sequence MEE

Arm description:

Control 1:
Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 4.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind, for migraine attack 3.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 4.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind, for migraine attack 3.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm title	Control 2 Sequence MEE

Arm description:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 3.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attack 4.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 3.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attack 4.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Number of subjects in period 1	100 mg Lasmiditan	200 mg Lasmiditan	Control 1 Sequence
Started	485	486	249
Treated at Least One Migraine Attack	485	486	249
Completed	403	394	219
Not completed	82	92	30
Physician decision	3	-	1
Consent withdrawn by subject	21	21	8
Adverse event, non-fatal	37	38	3
Migraines frequent-GP advised restart Topiramate	-	1	-
Pregnancy	1	2	-
Travel and coronavirus issues	-	-	-
Non-compliance with study drug	-	2	3
Participant did not want to take the 3 other tx	1	-	-

Lost to follow-up	9	7	4
Lack of efficacy	8	9	3
Protocol deviation	2	12	8

Number of subjects in period 1	Control 2 Sequence	100 mg Lasmiditan Maximum Extended Enrollment (MEE)	200 mg Lasmiditan MEE
Started	251	55	53
Treated at Least One Migraine Attack	251	55	53
Completed	223	45	46
Not completed	28	10	7
Physician decision	-	-	-
Consent withdrawn by subject	9	5	2
Adverse event, non-fatal	4	4	5
Migraines frequent-GP advised restart Topiramate	-	-	-
Pregnancy	-	-	-
Travel and coronavirus issues	1	-	-
Non-compliance with study drug	-	-	-
Participant did not want to take the 3 other tx	-	-	-
Lost to follow-up	6	1	-
Lack of efficacy	4	-	-
Protocol deviation	4	-	-

Number of subjects in period 1	Control 1 Sequence MEE	Control 2 Sequence MEE
Started	28	26
Treated at Least One Migraine Attack	28	26
Completed	26	23
Not completed	2	3
Physician decision	1	1
Consent withdrawn by subject	1	1
Adverse event, non-fatal	-	-
Migraines frequent-GP advised restart Topiramate	-	-
Pregnancy	-	-
Travel and coronavirus issues	-	-
Non-compliance with study drug	-	1
Participant did not want to take the 3 other tx	-	-
Lost to follow-up	-	-
Lack of efficacy	-	-
Protocol deviation	-	-

Period 2

Period 2 title	Open-Label Extension
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Open-Label Extension

Arm description:

Participants initially received 100 mg Lasmiditan at the first OLE visit, with flexible dosing (50, 100, or 200 mg) thereafter to optimize efficacy and tolerability.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	LY573144
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants initially received 100 mg Lasmiditan at the first OLE visit, with flexible dosing (50, 100, or 200 mg) thereafter to optimize efficacy and tolerability.

Number of subjects in period 2[1]	Open-Label Extension
Started	477
Treated at Least One Migraine Attack	476
Completed	324
Not completed	153
Participant refused to comply with face mask use	1
Physician decision	2
Participant wanted to become pregnant	1
Taking medication too restrictive for lifestyle	1
Participant didn't have disposition for OLE period	1
Consent withdrawn by subject	46
COVID-19	1
Adverse event, non-fatal	24
Death	1
Pregnancy	3
Non-compliance with study drug	5
Lost to follow-up	23

Protocol deviation	5
Lack of efficacy	39

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Reported are only those participants who were enrolled participate in the OLE.

Baseline characteristics

Reporting groups	
Reporting group title	Main Study
Reporting group description:	
All randomized participants who were treated with at least 1 dose of study drug, regardless of whether or not they undergo any study assessments.	

Reporting group values	Main Study	Total	
Number of subjects	1633	1633	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	41.30		
standard deviation	± 11.89	-	
Gender categorical Units: Subjects			
Female	1356	1356	
Male	277	277	
Ethnicity Units: Subjects			
Hispanic or Latino	135	135	
Not Hispanic or Latino	1232	1232	
Unknown or Not Reported	266	266	
Race Units: Subjects			
American Indian or Alaska Native	80	80	
Asian	374	374	
Black or African American	27	27	
Native Hawaiian or Other Pacific Islander	1	1	
White	1126	1126	
Multiple	3	3	
Missing	22	22	
Region of Enrollment Units: Subjects			
Austria	11	11	
Belgium	28	28	
China	281	281	
Denmark	30	30	
France	22	22	
Germany	275	275	
Hungary	17	17	
India	47	47	
Italy	22	22	
Mexico	95	95	
Netherlands	10	10	

Russian Federation	47	47	
Spain	61	61	
Switzerland	19	19	
United Kingdom	490	490	
United States	82	82	
Czechia	96	96	

End points reporting groups

Reporting group title	100 mg Lasmiditan

Reporting group description:

Participants received one 100 mg Lasmiditan tablet with one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	200 mg Lasmiditan

Reporting group description:

Participants received two 100 mg Lasmiditan tablets with one 50 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	Control 1 Sequence

Reporting group description:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 4.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind, for migraine attack 3.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	Control 2 Sequence

Reporting group description:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 3.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attack 4.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	100 mg Lasmiditan Maximum Extended Enrollment (MEE)

Reporting group description:

Participants received one 100 mg Lasmiditan tablet with one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	200 mg Lasmiditan MEE

Reporting group description:

Participants received two 100 mg Lasmiditan tablets with one 50 mg Lasmiditan matching placebo tablet to maintain blind. Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	Control 1 Sequence MEE

Reporting group description:

Control 1:
Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 4.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind, for migraine attack 3.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	Control 2 Sequence MEE

Reporting group description:

Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 3.
Participants received one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attack 4.
Tablets were administered orally within 4 hours of onset of a single migraine attack, up to 4 migraine attacks.

Reporting group title	Open-Label Extension

Reporting group description:

Participants initially received 100 mg Lasmiditan at the first OLE visit, with flexible dosing (50, 100, or

200 mg) thereafter to optimize efficacy and tolerability.

Subject analysis set title	Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who received 50 mg Lasmiditan matching placebo to treat migraine attacks 1, 2 and 4 in Control 1 Sequence or attacks 1, 2, and 3 in Control 2 Sequence.

Subject analysis set title	Control
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who received 50 mg Lasmiditan to treat migraine attack 3 in Control 1 Sequence and migraine attack 4 in Control 2 Sequence.

Primary: Percentage of Participants That Are Pain Free 2 Hours Postdose During the First Attack

End point title	Percentage of Participants That Are Pain Free 2 Hours Postdose During the First Attack[1]

End point description:

Pain-free is defined as mild, moderate, or severe headache pain becoming none at 2 hours postdose during the first attack.

Analysis Population Description (APD): All randomized participants who used at least 1 dose of study drug for an Intent-to-Treat (ITT) evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point type	Primary

End point timeframe:

2 Hours Postdose

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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: percentage of participants				
number (not applicable)	25.8	29.3	8.4	

Statistical analyses

Statistical analysis title	Pain Free 2 Hours Postdose First Attack 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.83

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.56
upper limit	8.73

Statistical analysis title	Pain Free 2 Hours Postdose First Attack 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.07
upper limit	6.77

Primary: Percentage of Participants That Are Pain Free at 2 Hours Postdose in at Least 2 Out of 3 Attacks

End point title	Percentage of Participants That Are Pain Free at 2 Hours Postdose in at Least 2 Out of 3 Attacks[2]

End point description:

To evaluate the 2 out of 3 primary consistency endpoint, the results of ITT evaluable attacks in the lasmiditan 100 mg and 200 mg groups will be assessed, and the ITT-evaluable attacks treated with placebo in the control group will be used for comparison. For participants with more than 3 ITT evaluable attacks, only the first 3 will be considered. Pain-free was defined as mild, moderate, or severe headache pain becoming none at the indicated assessment time.

APD: All randomized participants who experienced at least 2 successes or 2 failures during their first 2 or 3 ITT evaluable attacks. As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point type	Primary

End point timeframe:

2 Hours Postdose

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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	340	336	373	
Units: percentage of participants				
number (not applicable)	14.4	24.4	4.3	

Statistical analyses

Statistical analysis title	Pain Free in at Least 2 Out of 3 Attacks 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	713
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	6.76

Statistical analysis title	Pain Free in at Least 2 Out of 3 Attacks 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	709
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.13
upper limit	12.67

Secondary: Percentage of Participants That Are Pain Free 2 Hours Postdose During the First Attack in Triptan Insufficient Responders.

End point title	Percentage of Participants That Are Pain Free 2 Hours Postdose During the First Attack in Triptan Insufficient Responders.[3]

End point description:

Pain-free is defined as mild, moderate, or severe headache pain becoming none at 2 hours postdose

during the first attack. A triptan insufficient responder is defined as: 1) Scoring ≤5 on 4 questions from the Migraine Treatment Optimization Questionnaire (mTOQ-6) that defines participants with poor or very poor response to their current regimen; 2) Indicated they obtained pain freedom at 2 hours in 0 out of 3, or 1 out of 3 attacks when treated with the most recent triptan, or 3)Are not currently taking triptan and discontinued their most recent triptan due to lack of efficacy, tolerability issue, or contradictions to a past triptan.
APD: All randomized participants who were triptan insufficient responders and used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose.

End point type	Secondary

End point timeframe:

2 Hours Postdose

As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	183	203	193	
Units: percentage of participants				
number (not applicable)	24.0	25.6	8.8	

Statistical analyses

Statistical analysis title	Triptan Insufficient Responder 1st Attack 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	376
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	6.02

Statistical analysis title	Triptan Insufficient Responder 1st Attack 200 mg
Comparison groups	200 mg Lasmiditan v Placebo

Number of subjects included in analysis	396
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.97
upper limit	6.42

Secondary: Percentage of Participants That Are Pain Free at 2 Hours Postdose in at Least 2 Out of 3 Attacks in Triptan Insufficient Responders

End point title	Percentage of Participants That Are Pain Free at 2 Hours Postdose in at Least 2 Out of 3 Attacks in Triptan Insufficient Responders[4]

End point description:

Headache pain-free is defined as a reduction in pain severity from mild, moderate, or severe at baseline to none at the indicated assessment time. A subject is not counted as being pain-free at a specific time point if she or he used rescue or recurrence medication at or before the specific time point.

APD: All randomized participants who were triptan insufficient responders and experienced a sufficient number of successes or failures, (2 successes or 2 failures) during their first 2 or 3 ITT-evaluable attacks. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	17	31	7	
Units: percentage of participants				
number (not applicable)	11.0	20.1	4.3	

Statistical analyses

Statistical analysis title	TIR 2 out 3 Attacks 100 mg
Comparison groups	100 mg Lasmiditan v Placebo

Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.31
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	6.78

Statistical analysis title	TIR 2 Out of 3 Attacks 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	13.25

Secondary: Percentage of Participants With no Disability as Measured by the Disability Item, at 2 Hours Postdose During the First Attack

End point title	Percentage of Participants With no Disability as Measured by the Disability Item, at 2 Hours Postdose During the First Attack[5]

End point description:

Percentage of participants with no disability as measured by the disability item, at 2 hours postdose during the first attack. Disability was measured by determining the level of interference with normal activities with 4 response options including not at all; mild interference, marked interference; and need complete bed rest.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[5] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the

Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: percentage of participants				
number (not applicable)	18.6	19.8	9.5	

Statistical analyses

Statistical analysis title	Disability Item 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.48
upper limit	3.33

Statistical analysis title	Disability Item 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.65
upper limit	3.67

Secondary: Percentage of Participants With 24-Hour Sustained Pain Freedom During the First Attack

End point title	Percentage of Participants With 24-Hour Sustained Pain Freedom During the First Attack[6]

End point description:

Sustained pain freedom defined as pain free at 2 and 24 hours with no rescue medication.

APD: All randomized participants who received at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

24 Hours

Notes:

[6] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: percentage of participants				
number (not applicable)	13.6	17.3	4.3	

Statistical analyses

Statistical analysis title	24 Hour Sustained Pain Freedom 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.05
upper limit	6.02

Statistical analysis title	24 Hour Sustained Pain Freedom 200 mg
Comparison groups	200 mg Lasmiditan v Placebo

Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.77
upper limit	7.88

Secondary: Percentage of Participants With Pain Relief at 2 Hours Postdose in at Least 2 Out of 3 Attacks

End point title	Percentage of Participants With Pain Relief at 2 Hours Postdose in at Least 2 Out of 3 Attacks[7]

End point description:

Headache pain relief is defined as a reduction in pain severity from moderate to severe at baseline to mild or none at 2 hours postdose in at least 2 out of 3 attacks. To evaluate at least 2 out of 3 consistency endpoints, the results of ITT-evaluable attacks in the lasmiditan 100 mg and 200 mg groups will be assessed, and the ITT-evaluable attacks treated with placebo in the control group will be used for comparison. For patients with more than 3 ITT-evaluable attacks, only the first 3 with the same treatment will be considered.

APD: All randomized participants who experienced a sufficient number of successes or failures, (2 successes or 2 failures) during their first 2 or 3 ITT-evaluable attacks. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[7] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	332	333	320	
Units: percentage of participants				
number (not applicable)	62.3	66.7	36.9	

Statistical analyses

Statistical analysis title	Pain Relief 2 out of 3 Attacks 100 mg
Comparison groups	100 mg Lasmiditan v Placebo

Number of subjects included in analysis	652
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.11
upper limit	4.01

Statistical analysis title	Pain Relief 2 out of 3 Attacks 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	653
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.53
upper limit	4.85

Secondary: Percentage of Participants Free of Most Bothersome Symptom (MBS) Associated With Migraine at 2 Hours Postdose During the First Attack

End point title	Percentage of Participants Free of Most Bothersome Symptom (MBS) Associated With Migraine at 2 Hours Postdose During the First Attack[8]

End point description:

MBS freedom is defined as the absence of the associated symptom of migraine (nausea, phonophobia, or photophobia) at the indicated assessment time that was identified at baseline as the most bothersome symptom.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[8] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	376	395	396	
Units: percentage of participants				
number (not applicable)	40.4	39.0	28.0	

Statistical analyses

Statistical analysis title	Free of MBS 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	772
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.29
upper limit	2.35

Statistical analysis title	Free of MBS 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	791
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.63
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.21
upper limit	2.2

Secondary: Percentage of Participants With Pain Relief at 2 Hours Post Dose During the First Attack

End point title	Percentage of Participants With Pain Relief at 2 Hours Post Dose During the First Attack[9]

End point description:

Headache pain-relief is defined as a reduction in pain severity from moderate or severe at baseline to

mild or none, or a reduction in pain severity from mild at baseline to none, at the indicated assessment time.

APD: All randomized participants who use at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[9] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: percentage of participants				
number (not applicable)	65.4	65.2	41.3	

Statistical analyses

Statistical analysis title	Pain Relief 2 Hours Postdose 1st Attack 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.05
upper limit	3.57

Statistical analysis title	Pain Relief 2 Hours Postdose 1st Attack 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.68

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.04
upper limit	3.53

Secondary: Percentage of Participants Requiring Rescue Medication for Migraine Within 24 Hours of Treatment During the First Attack

End point title	Percentage of Participants Requiring Rescue Medication for Migraine Within 24 Hours of Treatment During the First Attack[10]

End point description:

Percentage of participants requiring rescue medication for migraine within 2 to 24 hours of treatment during the first attack.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

24 Hours

Notes:

[10] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	311	307	406	
Units: percentage of participants				
number (not applicable)	19.6	19.2	29.3	

Statistical analyses

Statistical analysis title	Rescue Medication 1st Attack 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	717
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.46

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	0.65

Statistical analysis title	Rescue Medication 1st Attack 200 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	717
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	0.6

Secondary: Percentage of Participants That Are Free of Symptoms Associated With Migraine at 2 Hours Postdose During the First Attack

End point title	Percentage of Participants That Are Free of Symptoms Associated With Migraine at 2 Hours Postdose During the First Attack[11]

End point description:

Total migraine freedom is defined as no pain and no migraine associated symptoms (photophobia, phonophobia, nausea, and vomiting) at 2 hours postdose during the first attack.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[11] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: percentage of participants				
number (not applicable)	17.9	21.0	7.2	

Statistical analyses

Statistical analysis title	Free of Migraine Associated Symptoms 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.79
upper limit	4.28

Statistical analysis title	Free of Migraine Associated Symptoms 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	5.15

Secondary: Percentage of Participants With Migraine Recurrence at 24 Hours During the First Attack

End point title	Percentage of Participants With Migraine Recurrence at 24 Hours During the First Attack[12]

End point description:

Percentage of participants with migraine recurrence at 24 hours during the first attack defined as return

of any headache in participants who were pain free at 2 hours.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

24 hours

Notes:

[12] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	108	127	37	
Units: percentage of participants				
number (not applicable)	30.6	22.0	37.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Pain Freedom, Pain Relief, Freedom From MBS, and No Disability Postdose During First Attack

End point title	Percentage of Participants With Pain Freedom, Pain Relief, Freedom From MBS, and No Disability Postdose During First Attack[13]

End point description:

Percentage of participants with pain freedom, pain relief, freedom from MBS, and no disability postdose during first attack.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

30 Minutes (Min) and 1 Hour (Hr) Postdose

Notes:

[13] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: Percentage of Participants				
number (not applicable)				
Pain Freedom (30 Min)	1.4	1.6	0.2	
Pain Freedom (1 Hr)	6.0	12.7	2.0	
Pain Relief (30 Min)	18.6	22.4	14.0	
Pain Relief (1 Hr)	48.7	47.2	29.3	
Freedom from MBS (30 Min)	12.5	14.4	11.4	
Freedom from MBS (1 Hr)	23.7	28.9	22.0	
No Disability Postdose During 1st Attack (30 Min)	3.1	2.3	2.3	
No Disability Postdose During First Attack (1 Hr)	6.0	9.9	5.0	

Statistical analyses

Statistical analysis title	Pain Freedom 30 Min Postdose 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.086
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	53.37

Statistical analysis title	Pain Freedom 30 Min. Postdose 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.065
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	59.08

Statistical analysis title	Pain Freedom 1 Hour Postdose
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.42
upper limit	6.68

Statistical analysis title	Pain Freedom 1 Hour Postdose
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.43
upper limit	14.44

Statistical analysis title	Pain Relief 30 Min Postdose 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.065
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	2.03

Statistical analysis title	Pain Relief 30 Min Postdose 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	2.52

Statistical analysis title	Pain Relief 1 Hour Postdose 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.74
upper limit	3.06

Statistical analysis title	Pain Relief 1 Hour Postdose 200 mg
Comparison groups	200 mg Lasmiditan v Placebo

Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.64
upper limit	2.88

Statistical analysis title	Freedom from MBS 30 Min 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.651
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.71

Statistical analysis title	Freedom from MBS 30 Min 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.98

Statistical analysis title	Freedom from MBS 1 Hour 100 mg

Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.593
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.54

Statistical analysis title	Freedom from MBS 1 Hour 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.98

Secondary: Change from Baseline in Total Score as Measured by the Migraine Disability Assessment Test (MIDAS) Scale

End point title	Change from Baseline in Total Score as Measured by the Migraine Disability Assessment Test (MIDAS) Scale[14]

End point description:

The MIDAS is a participant-rated scale which was designed to quantify headache-related disability over a 3-month period. This instrument consists of 5 items that reflect the number of days reported as missed, or with reduced productivity at work or home and social events. Each question is answered as the number of days during the past 3 months of assessment, ranging from 0 to 90, with the total score being the summation of the 5 numeric responses. A higher value is indicative of more disability.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Notes:

[14] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Control	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	447	437	451	
Units: Score on a Scale				
arithmetic mean (standard deviation)	-10.7 (± 24.36)	-12.0 (± 21.38)	-13.1 (± 21.40)	

Statistical analyses

Statistical analysis title	Change from Baseline MIDAS 100 mg
Comparison groups	100 mg Lasmiditan v Control
Number of subjects included in analysis	898
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.092
Method	ANCOVA

Statistical analysis title	Change from Baseline MIDAS 200 mg
Comparison groups	200 mg Lasmiditan v Control
Number of subjects included in analysis	888
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.211
Method	ANCOVA

Secondary: Percentage of Participants Very much Better or Much Better as Measured by Patient Global Impression of Change (PGI-C) at 2 Hours Postdose During the First Attack

End point title	Percentage of Participants Very much Better or Much Better as Measured by Patient Global Impression of Change (PGI-C) at 2 Hours Postdose During the First Attack[15]

End point description:

The PGI-C is a one-item questionnaire that asks participants to provide their impression of change since taking the medicine. The PGI-C is measured using a 7-point Likert scale, with 1 = very much better, 2 = much better, 3 = a little better, 4 = no change, 5 = a little worse, 6 = much worse, and 7 = very much worse. Reported are participants whose combined impression of change since taking the medicine was very much better and much better at 2 hours postdose.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported

for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[15] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: Percentage of Participants				
number (not applicable)	29.8	30.0	13.3	

Statistical analyses

Statistical analysis title	PGI-C 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.01
upper limit	4.05

Statistical analysis title	PGI-C 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.12
upper limit	4.26

Secondary: Migraine Quality of Life Questionnaire (MQoLQ) Score at 24 Hours Post First Dose of Study During First Attack

End point title	Migraine Quality of Life Questionnaire (MQoLQ) Score at 24 Hours Post First Dose of Study During First Attack[16]

End point description:

The 24-hour Migraine Quality of Life Questionnaire (24-hr MQoLQ) has been specifically developed to measure the HRQoL of patients with migraine within a 24-hour period after having taken migraine medication A domain score is calculated by summing the responses to the 3 questions and the domain score ranges from 3 to 21, with lower scores indicating less impairment. The questionnaire will be administered 24 hours after dosing with study drug during each migraine. The analysis of variance (ANOVA) model was used with region and treatment adjusted for the overall treatment effect.

APD: All randomized participants who used at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

24 Hours Post First Dose

Notes:

[16] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	289	303	293	
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Social Functioning	12.4 (± 4.8)	12.1 (± 4.7)	11.7 (± 4.7)	
Migraine Symptoms	12.4 (± 4.1)	12.5 (± 4.2)	11.4 (± 4.4)	
Feeling/Concern	11.2 (± 4.5)	11.2 (± 4.5)	10.3 (± 4.2)	

Statistical analyses

Statistical analysis title	Social Functioning 100 mg
Comparison groups	100 mg Lasmiditan v Placebo

Number of subjects included in analysis	582
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.056
Method	ANOVA

Statistical analysis title	Social Functioning 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	596
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.267
Method	ANOVA

Statistical analysis title	Migraine Symptoms 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	582
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	ANOVA

Statistical analysis title	Migraine Symptoms 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	596
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANOVA

Statistical analysis title	Feeling/Concerns 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	582
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	ANOVA

Statistical analysis title	Feelings/Concerns 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	596
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.018
Method	ANOVA

Secondary: Percentage of Participants Satisfied With Their Treatment Measured by a 4-Item Questionnaire

End point title	Percentage of Participants Satisfied With Their Treatment Measured by a 4-Item Questionnaire[17]

End point description:

Treatment satisfaction was evaluated at the End of Study (EoS) visit by determining the participant's level of satisfaction (ranging from extremely dissatisfied to extremely satisfied); their willingness to take this treatment again (ranging from strongly disagree to strongly agree) and if they would they recommend this treatment to another participants (ranging from strongly disagree to strongly agree).

APD: All randomized participants who use at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[17] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Control	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	452	444	460	
Units: Percentage of Participants				
number (not applicable)				
Recommend Treatment - Agree/Strongly Agree	57.2	58.1	52.0	
Willing to Take Treatment - Agree/Strongly Agree	61.5	58.9	64.3	
Extremely/Very Satisfied/Satisfied with Medication	48.9	51.6	43.5	
Prefer This Treatment	31.2	32.7	29.1	

Statistical analyses

Statistical analysis title	Recommend Treatment - Agree/Strongly Agree 100 mg

Statistical analysis description:

Agree and Strongly Agree

Comparison groups	100 mg Lasmiditan v Control
Number of subjects included in analysis	912
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.101
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.62

Statistical analysis title	Recommend Treatment - Agree/Strongly Agree 200 mg
Statistical analysis description: Agree and Strongly Agree	
Comparison groups	200 mg Lasmiditan v Control
Number of subjects included in analysis	904
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.063
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.67

Statistical analysis title	Take Treatment Again - Agree/Strongly Agree 100 mg
Statistical analysis description: Agree and Strongly Agree	
Comparison groups	100 mg Lasmiditan v Control
Number of subjects included in analysis	912
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.376
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.89

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.16

Statistical analysis title	Take Treatment Again - Agree/Strongly Agree 200 mg
Statistical analysis description: Agree and Strongly Agree	
Comparison groups	200 mg Lasmiditan v Control
Number of subjects included in analysis	904
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.082
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.03

Statistical analysis title	Extremely/Very/ Satisfied with Medication 100 mg
Statistical analysis description: Extremely/Very Satisfied and Satisfied	
Comparison groups	100 mg Lasmiditan v Control
Number of subjects included in analysis	912
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.096
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.62

Statistical analysis title	Extremely/Very/ Satisfied with Medication 200 mg
Statistical analysis description: Extremely/Very Satisfied and Satisfied	
Comparison groups	200 mg Lasmiditan v Control

Number of subjects included in analysis	904
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.06
upper limit	1.8

Statistical analysis title	Prefer This Treatment 100 mg
Comparison groups	100 mg Lasmiditan v Control
Number of subjects included in analysis	912
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.445
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.49

Statistical analysis title	Prefer This Treatment 200 mg
Comparison groups	200 mg Lasmiditan v Control
Number of subjects included in analysis	904
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.243
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.58

Secondary: Change From Baseline in Utility at 24 Hours Postdose as Measured by

the EuroQol 5-Dimension 5-Level Scale (EQ-5D-5L) at 24 Hours Postdose During First Attack

End point title	Change From Baseline in Utility at 24 Hours Postdose as Measured by the EuroQol 5-Dimension 5-Level Scale (EQ-5D-5L) at 24 Hours Postdose During First Attack[18]

End point description:

The EQ-5D-5L questionnaire is a participant-rated scale that assesses health status, it consists of 2 parts. The first part assesses 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) that have 5 possible levels of response (no problems, slight problems, moderate problems, severe problems, extreme problems).The EQ-5D can be used to generate a health state index score, which is used to compute quality-adjusted life years for utilization in health economic analyses. The health state index score is calculated based on the responses to the 5 dimensions, providing a single value on a scale from less than 0 (where 0 is a health state equivalent to death) to 1 (perfect health), with higher scores indicating better health utility. ANCOVA was used to assess the effect of Lasmiditan over placebo or control. The model includes fixed categorical effect of treatment and geographic region and baseline as covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 hr Postdose

APD: All randomized participants who use at least 1 dose of study drug for an ITT evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours pos

Notes:

[18] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: Score on a Scale				
arithmetic mean (standard deviation)	0.2499 (± 0.25788)	0.2271 (± 0.29854)	0.2122 (± 0.25729)	

Statistical analyses

Statistical analysis title	EQ-5D-5L for First Attack
Comparison groups	100 mg Lasmiditan v 200 mg Lasmiditan v Placebo
Number of subjects included in analysis	1296
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.142
Method	ANCOVA

Secondary: Percentage of Participants That Are Pain Free at 2 Hours Postdose in at Least 3 Out of 4 Attacks

End point title	Percentage of Participants That Are Pain Free at 2 Hours Postdose in at Least 3 Out of 4 Attacks[19]

End point description:

Headache pain-free is defined as a reduction in pain severity from mild, moderate, or severe to none at the indicated assessment time (2 hours postdose). To evaluate 3 out of 4 consistency endpoints; all ITT-evaluable attacks will be used. For the control group, the results of all ITT-evaluable attacks treated with lasmiditan 50 mg or placebo will be included. The control group is used for comparison. The population for 3 out of 4 consistency endpoints with sufficient number of successes or failures is defined as all patients who experienced at least 3 successes or 2 failures during ITT-evaluable attacks.

APD: All randomized participants who experienced a sufficient number of successes or failures, (3 out of 4 attacks) during ITT evaluable attacks for any of the consistency analyses. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[19] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Control	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	325	306	387	
Units: Percentage of Participants				
number (not applicable)	7.4	10.8	2.6	

Statistical analyses

Statistical analysis title	Pain Free 3 out of 4 Attacks 100 mg
Comparison groups	100 mg Lasmiditan v Control
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.42
upper limit	6.4

Statistical analysis title	Pain Free 3 out of 4 Attacks 200 mg
Comparison groups	200 mg Lasmiditan v Control

Number of subjects included in analysis	693
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.22
upper limit	9.47

Secondary: Percentage of Participants With Pain Relief at 2 Hours Postdose in at Least 3 Out of 4 Attacks

End point title	Percentage of Participants With Pain Relief at 2 Hours Postdose in at Least 3 Out of 4 Attacks[20]

End point description:

Headache pain-relief is defined as a reduction in pain severity from moderate or severe at baseline to mild or none, or a reduction in pain severity from mild at baseline to none, at the indicated assessment time (2 hours postdose). To evaluate 3 out of 4 consistency endpoints; all ITT-evaluable attacks will be used. For the control group, the results of all ITT-evaluable attacks treated with lasmiditan 50 mg or placebo will be included. The control group is used for comparison. The population for 3 out of 4 consistency endpoints with sufficient number of successes or failures is defined as all patients who experienced at least 3 successes or 2 failures during ITT-evaluable attacks.

APD: All randomized participants who experienced a sufficient number of successes or failures, (3 successes or 2 failures) during ITT-evaluable attacks for any of the consistency analyses. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[20] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Control	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	260	235	317	
Units: Percentage of Participants				
number (not applicable)	40.8	49.8	21.8	

Statistical analyses

Statistical analysis title	Pain Relief 3 Out of 4 Attacks 100 mg
Comparison groups	100 mg Lasmiditan v Control

Number of subjects included in analysis	577
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.74
upper limit	3.62

Statistical analysis title	Pain Relief 3 Out of 4 Attacks 200 mg
Comparison groups	200 mg Lasmiditan v Control
Number of subjects included in analysis	552
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	5.2

Secondary: Percentage of Participants with Associated Migraines Symptoms of Nausea, Vomiting, Photophobia, and Phonophobia Present at 2 Hours Postdose for First Attack

End point title	Percentage of Participants with Associated Migraines Symptoms of Nausea, Vomiting, Photophobia, and Phonophobia Present at 2 Hours Postdose for First Attack[21]

End point description:

Presence of associated migraine symptoms at 2 hours postdose at first migraine attack, including each of the following: phonophobia, photophobia, nausea, and vomiting.

APD: All randomized participants who used at least 1 dose of study drug for an Intent-to-Treat (ITT) evaluable attack, defined as a treated attack of at least mild pain severity with any postdose pain severity assessments at or before 2 hours postdose. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

2 Hours Postdose

Notes:

[21] - 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: As pre-specified in the analysis plan, outcome measures will not be reported for the

Maximum Extended Enrollment (MEE) arms/groups but only for the main global study arms/groups.

End point values	100 mg Lasmiditan	200 mg Lasmiditan	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	419	434	443	
Units: percentage of participants				
number (not applicable)				
Nausea	29.1	29.0	29.1	
Phonophobia	26.7	23.5	40.6	
Photophobia	38.2	39.9	55.3	
Vomiting	1.2	3.0	2.7	

Statistical analyses

Statistical analysis title	Nausea 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.953
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.36

Statistical analysis title	Nausea 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.768
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.41

Statistical analysis title	Phonophobia 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.71

Statistical analysis title	Phonophobia 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	0.62

Statistical analysis title	Photophobia 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.48

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.63

Statistical analysis title	Photophobia 200 mg
Comparison groups	200 mg Lasmiditan v Placebo
Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.71

Statistical analysis title	Vomiting 100 mg
Comparison groups	100 mg Lasmiditan v Placebo
Number of subjects included in analysis	862
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.129
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	1.25

Statistical analysis title	Vomiting 200 mg
Comparison groups	200 mg Lasmiditan v Placebo

Number of subjects included in analysis	877
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.769
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	2.43

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 16 months

Adverse event reporting additional description:

All randomized participants who take at least 1 dose of study drug, regardless of whether or not they undergo any study assessments. Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	100 Milligram (mg) Lasmiditan

Reporting group description:

Participants received one 100 mg Lasmiditan tablet with one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind.

Reporting group title	200 mg Lasmiditan

Reporting group description:

Participants received two 100 mg Lasmiditan tablets with one 50 mg Lasmiditan matching placebo tablet to maintain blind.

Reporting group title	Main - Control

Reporting group description:

Control 1 Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 4, and one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind, for migraine attack 3.
Control 2 Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 3, and one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attack 4.

Reporting group title	100 mg Lasmiditan - MEE

Reporting group description:

Participants received one 100 mg Lasmiditan tablet with one 50 mg Lasmiditan matching placebo tablet and one 100 mg Lasmiditan matching placebo tablet to maintain blind.

Reporting group title	200 mg Lasmiditan - MEE

Reporting group description:

Participants received two 100 mg Lasmiditan tablets with one 50 mg Lasmiditan matching placebo tablet to maintain blind.

Reporting group title	MEE - Control

Reporting group description:

Control 1 Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 4, and one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind, for migraine attack 3.
Control 2 Participants received one 50 mg Lasmiditan matching placebo tablet and two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attacks 1, 2, and 3, and one 50 mg Lasmiditan tablet with two 100 mg Lasmiditan matching placebo tablets to maintain blind for migraine attack 4.

Reporting group title	Open Label Extension

Reporting group description:

Participants initially received 100 mg Lasmiditan at the first OLE visit, with flexible dosing (50, 100, or 200 mg) thereafter to optimize efficacy and tolerability.

Serious adverse events	100 Milligram (mg) Lasmiditan	200 mg Lasmiditan	Main - Control
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 485 (1.44%)	8 / 486 (1.65%)	7 / 500 (1.40%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm malignant			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
mucinous adenocarcinoma of appendix			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
nasopharyngeal cancer stage iii			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (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			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[1]	0 / 403 (0.00%)	0 / 418 (0.00%)	0 / 416 (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
Surgical and medical procedures			
appendicectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 403 (0.00%)	0 / 418 (0.00%)	0 / 416 (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
General disorders and administration site conditions			
cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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			
endometriosis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[3]	0 / 403 (0.00%)	0 / 418 (0.00%)	1 / 416 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 403 (0.00%)	1 / 418 (0.24%)	0 / 416 (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
intermenstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	1 / 403 (0.25%)	0 / 418 (0.00%)	0 / 416 (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
ovarian cyst torsion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 403 (0.00%)	0 / 418 (0.00%)	0 / 416 (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
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
suicidal ideation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
comminuted fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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			
angina unstable			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
palpitations			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
wolff-parkinson-white syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiplegic migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (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
medication overuse headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ophthalmic migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
sensory loss			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (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
serotonin syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (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
vestibular migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (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
Eye disorders			
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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			
haemorrhoids thrombosed			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
liver disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess oral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (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
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (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
covid-19			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
diverticulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (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
otitis media			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (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	100 mg Lasmiditan - MEE	200 mg Lasmiditan - MEE	MEE - Control
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	0 / 54 (0.00%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
lung neoplasm malignant			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
mucinous adenocarcinoma of appendix			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
nasopharyngeal cancer stage iii			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[1]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Surgical and medical procedures			
appendicectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
General disorders and administration site conditions			
cyst			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
endometriosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
intermenstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
ovarian cyst torsion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Respiratory, thoracic and mediastinal disorders			
asthma			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Psychiatric disorders			
suicidal ideation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
comminuted fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
ligament rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
lower limb fracture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
angina unstable			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
palpitations			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
wolff-parkinson-white syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
hemiplegic migraine			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
medication overuse headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	0 / 54 (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
ophthalmic migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
sensory loss			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
serotonin syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
vestibular migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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

Eye disorders			
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
haemorrhoids thrombosed			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
liver disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
abscess oral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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

bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
diverticulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
otitis media			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (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	Open Label Extension		
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 477 (3.98%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lung neoplasm malignant				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
mucinous adenocarcinoma of appendix				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
nasopharyngeal cancer stage iii				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine leiomyoma				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[1]	1 / 413 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
appendicectomy				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
abortion spontaneous				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed[2]	2 / 413 (0.48%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
endometriosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 477 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 477 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intermenstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 477 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ovarian cyst torsion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[6]	1 / 413 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
suicidal ideation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
comminuted fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ligament rupture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lower limb fracture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tibia fracture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
angina unstable				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
palpitations				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
wolff-parkinson-white syndrome				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
headache				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hemiplegic migraine				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
medication overuse headache				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
migraine				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
ophthalmic migraine				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
sensory loss				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
serotonin syndrome				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

vestibular migraine				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
optic ischaemic neuropathy				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
haemorrhoids thrombosed				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vomiting				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
liver disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
abscess oral				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

appendicitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
bronchitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
covid-19				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
diverticulitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
otitis media				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	100 Milligram (mg) Lasmiditan	200 mg Lasmiditan	Main - Control
Total subjects affected by non-serious adverse events			
subjects affected / exposed	331 / 485 (68.25%)	355 / 486 (73.05%)	184 / 500 (36.80%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
lipoma of breast			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 403 (0.00%)	0 / 418 (0.00%)	1 / 416 (0.24%)
occurrences (all)	0	0	1
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	4	0	0
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	3 / 485 (0.62%)	2 / 486 (0.41%)	4 / 500 (0.80%)
occurrences (all)	6	2	4
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	0	1	1
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
peripheral coldness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
poor peripheral circulation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
antibiotic prophylaxis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
tooth restoration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	23 / 485 (4.74%)	31 / 486 (6.38%)	3 / 500 (0.60%)
occurrences (all)	32	51	4
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	4 / 486 (0.82%)	3 / 500 (0.60%)
occurrences (all)	4	7	3
chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 485 (1.03%)	5 / 486 (1.03%)	3 / 500 (0.60%)
occurrences (all)	6	5	4
discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 485 (1.03%)	7 / 486 (1.44%)	1 / 500 (0.20%)
occurrences (all)	6	11	1
fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	55 / 485 (11.34%)	71 / 486 (14.61%)	19 / 500 (3.80%)
occurrences (all)	80	104	21
feeling abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 485 (1.86%)	19 / 486 (3.91%)	2 / 500 (0.40%)
occurrences (all)	9	25	2
feeling cold			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 485 (1.24%)	1 / 486 (0.21%)	2 / 500 (0.40%)
occurrences (all)	11	1	2
feeling drunk			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	6	2	0

feeling hot			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	6 / 486 (1.23%)	2 / 500 (0.40%)
occurrences (all)	4	8	2
feeling of body temperature change			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
feeling of relaxation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	2	0
gait disturbance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	4 / 486 (0.82%)	0 / 500 (0.00%)
occurrences (all)	5	4	0
general physical health deterioration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
hunger			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
illness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	0	2	0
influenza like illness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	1	2	0
malaise			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	6 / 485 (1.24%)	7 / 486 (1.44%)	2 / 500 (0.40%)
occurrences (all)	9	9	2
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	2	1	1
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	2
pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	2 / 486 (0.41%)	1 / 500 (0.20%)
occurrences (all)	3	2	1
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	2 / 500 (0.40%)
occurrences (all)	0	3	2
sense of oppression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
sensation of foreign body			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
sensation of blood flow			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1

swelling face			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
thirst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	3 / 486 (0.62%)	1 / 500 (0.20%)
occurrences (all)	2	3	1
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
seasonal allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
cervix inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[8]	0 / 403 (0.00%)	0 / 418 (0.00%)	0 / 416 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	1 / 403 (0.25%)	0 / 418 (0.00%)	0 / 416 (0.00%)
occurrences (all)	1	0	0
endometriosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[10]	0 / 403 (0.00%)	0 / 418 (0.00%)	0 / 416 (0.00%)
occurrences (all)	0	0	0
erection increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 82 (0.00%)	1 / 68 (1.47%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
intermenstrual bleeding			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[12]	0 / 403 (0.00%)	0 / 418 (0.00%)	1 / 416 (0.24%)
occurrences (all)	0	0	1
menstruation irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[13]	0 / 403 (0.00%)	1 / 418 (0.24%)	0 / 416 (0.00%)
occurrences (all)	0	1	0
menstrual disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[14]	1 / 403 (0.25%)	0 / 418 (0.00%)	0 / 416 (0.00%)
occurrences (all)	1	0	0
pelvic pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
polymenorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[15]	0 / 403 (0.00%)	0 / 418 (0.00%)	1 / 416 (0.24%)
occurrences (all)	0	0	1
vaginal haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[16]	0 / 403 (0.00%)	1 / 418 (0.24%)	0 / 416 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	2 / 500 (0.40%)
occurrences (all)	0	2	4
dry throat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
dysphonia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 485 (1.03%)	2 / 486 (0.41%)	1 / 500 (0.20%)
occurrences (all)	5	2	1
epistaxis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	2	0	0
hyperventilation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
mouth breathing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	3	0	1
rhinalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1

rhinitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
sinonasal obstruction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
sinus pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
tachypnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
yawning			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
abnormal dreams			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 485 (1.03%)	6 / 486 (1.23%)	1 / 500 (0.20%)
occurrences (all)	5	9	1
aggression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	2	0	0
agitation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	2 / 485 (0.41%)	4 / 486 (0.82%)	1 / 500 (0.20%)
occurrences (all)	2	4	1
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 485 (1.24%)	10 / 486 (2.06%)	4 / 500 (0.80%)
occurrences (all)	8	11	4
apathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
bradyphrenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
confusional state			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	6 / 486 (1.23%)	0 / 500 (0.00%)
occurrences (all)	2	6	0
daydreaming			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	7 / 486 (1.44%)	4 / 500 (0.80%)
occurrences (all)	4	8	4
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0

depressive symptom			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
derealisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
disorganised speech			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
dissociation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
disorientation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	3 / 486 (0.62%)	0 / 500 (0.00%)
occurrences (all)	3	3	0
dyssomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
emotional disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
emotional distress			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
euphoric mood			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	2 / 485 (0.41%)	3 / 486 (0.62%)	1 / 500 (0.20%)
occurrences (all)	2	4	2
fear			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
hallucination			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
hallucination, auditory			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	2	0
hallucination, visual			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	6 / 486 (1.23%)	0 / 500 (0.00%)
occurrences (all)	7	6	0
hypnagogic hallucination			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 485 (1.24%)	11 / 486 (2.26%)	4 / 500 (0.80%)
occurrences (all)	8	20	4
irritability			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	1	2	0
mood altered			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0

nervousness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	1 / 500 (0.20%)
occurrences (all)	0	2	1
nightmare			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	4 / 486 (0.82%)	1 / 500 (0.20%)
occurrences (all)	4	5	1
poor quality sleep			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
psychomotor retardation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
rapid eye movements sleep abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	6 / 486 (1.23%)	3 / 500 (0.60%)
occurrences (all)	3	9	3
sleep disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	5 / 486 (1.03%)	0 / 500 (0.00%)
occurrences (all)	1	7	0
somatic symptom disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	3	0	0
suicidal ideation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
Investigations			
blood cholesterol increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
blood folate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
blood pressure decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
body temperature increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
electrocardiogram t wave abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
heart rate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
heart rate increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	5	1	1
heart rate irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
intraocular pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
liver function test abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
muscle strength abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1

pulse abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	2	0	0
total bile acids increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
accidental overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
eye contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
joint dislocation			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
joint injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	1	0	1
muscle rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
skin abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
soft tissue injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
bradycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	0	1	1
cardiovascular disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
palpitations			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	12 / 485 (2.47%)	7 / 486 (1.44%)	3 / 500 (0.60%)
occurrences (all)	19	9	3
supraventricular extrasystoles			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
supraventricular tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	5	2	0
Nervous system disorders			
ageusia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
allodynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
altered state of consciousness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	3	0
amnesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
anosmia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
aphasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	3 / 486 (0.62%)	0 / 500 (0.00%)
occurrences (all)	0	3	0
ataxia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	1	3	0
aura			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0

balance disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	10 / 485 (2.06%)	13 / 486 (2.67%)	2 / 500 (0.40%)
occurrences (all)	15	15	2
bradykinesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
clumsiness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
cognitive disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	1	2	0
coordination abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	3 / 486 (0.62%)	0 / 500 (0.00%)
occurrences (all)	2	4	0
depressed level of consciousness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	2	0	0
disturbance in attention			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 485 (1.44%)	11 / 486 (2.26%)	1 / 500 (0.20%)
occurrences (all)	9	11	1
dizziness			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	155 / 485 (31.96%)	187 / 486 (38.48%)	44 / 500 (8.80%)
occurrences (all)	230	325	59
dizziness postural alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	0 / 486 (0.00%)	2 / 500 (0.40%)
occurrences (all)	4	0	2
dysaesthesia alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
dysarthria alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	7 / 486 (1.44%)	0 / 500 (0.00%)
occurrences (all)	1	7	0
dysgeusia alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	1	1	1
dyskinesia alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	0	2	0
dysstasia alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
fine motor skill dysfunction alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	0	3	0
formication alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	4	2	0

head discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	3 / 486 (0.62%)	2 / 500 (0.40%)
occurrences (all)	4	4	2
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 485 (1.86%)	9 / 486 (1.85%)	7 / 500 (1.40%)
occurrences (all)	9	10	8
hemiparesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
hypersomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	3	4	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	24 / 485 (4.95%)	16 / 486 (3.29%)	7 / 500 (1.40%)
occurrences (all)	33	24	9
hypotonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	1	3	0
lethargy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 485 (1.03%)	7 / 486 (1.44%)	0 / 500 (0.00%)
occurrences (all)	6	11	0
memory impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	2	0	2
mental impairment			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	2	1	0
migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	1 / 486 (0.21%)	2 / 500 (0.40%)
occurrences (all)	4	1	2
migraine with aura			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
muscle contractions involuntary			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
muscle spasticity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
myoclonus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	72 / 485 (14.85%)	93 / 486 (19.14%)	21 / 500 (4.20%)
occurrences (all)	103	170	25
presyncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	2 / 486 (0.41%)	1 / 500 (0.20%)
occurrences (all)	4	2	1
psychomotor hyperactivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0

restless legs syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	4 / 486 (0.82%)	1 / 500 (0.20%)
occurrences (all)	6	6	1
sedation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	3	0	0
sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	0	1	1
sensorimotor disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
sensory disturbance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
sensory loss			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
serotonin syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
slow speech			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	0	2	0
somnolence			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	32 / 485 (6.60%)	54 / 486 (11.11%)	12 / 500 (2.40%)
occurrences (all)	48	82	12
speech disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	1	2	0
syncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
taste disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
tension headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	1 / 486 (0.21%)	2 / 500 (0.40%)
occurrences (all)	2	3	4
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 485 (1.65%)	13 / 486 (2.67%)	3 / 500 (0.60%)
occurrences (all)	8	21	3
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
microcytic anaemia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
acute vestibular syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	2	0
conductive deafness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
deafness transitory			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	2	0	0
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
hyperacusis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	1	0	1
motion sickness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	5 / 485 (1.03%)	9 / 486 (1.85%)	1 / 500 (0.20%)
occurrences (all)	5	10	1
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	45 / 485 (9.28%)	47 / 486 (9.67%)	7 / 500 (1.40%)
occurrences (all)	68	79	7
vertigo positional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	3	0	0
Eye disorders			
abnormal sensation in eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
blepharospasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
cataract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
diplopia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	3 / 486 (0.62%)	0 / 500 (0.00%)
occurrences (all)	0	4	0
eye movement disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
eye pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
eyelid ptosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
eyelid skin dryness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
metamorphopsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
mydriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
ocular discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
ocular hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
photophobia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	4 / 486 (0.82%)	1 / 500 (0.20%)
occurrences (all)	3	5	1

photopsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	5 / 486 (1.03%)	0 / 500 (0.00%)
occurrences (all)	3	6	0
pupillary reflex impaired			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
vision blurred			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 485 (1.03%)	9 / 486 (1.85%)	0 / 500 (0.00%)
occurrences (all)	5	12	0
visual field defect			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
visual impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	7 / 486 (1.44%)	0 / 500 (0.00%)
occurrences (all)	2	11	0
vitreous haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
abdominal discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	3 / 486 (0.62%)	1 / 500 (0.20%)
occurrences (all)	0	4	1
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	4 / 486 (0.82%)	11 / 500 (2.20%)
occurrences (all)	1	6	14
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	3 / 486 (0.62%)	1 / 500 (0.20%)
occurrences (all)	4	3	1
colitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 485 (1.44%)	6 / 486 (1.23%)	8 / 500 (1.60%)
occurrences (all)	9	9	9
dry mouth			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 485 (1.24%)	11 / 486 (2.26%)	1 / 500 (0.20%)
occurrences (all)	9	15	3
dyspepsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	3 / 486 (0.62%)	2 / 500 (0.40%)
occurrences (all)	3	3	2
epigastric discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
flatulence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	1	2	1
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	2 / 500 (0.40%)
occurrences (all)	2	0	3

gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	1 / 500 (0.20%)
occurrences (all)	0	5	1
glossodynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
hypoaesthesia oral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	6 / 486 (1.23%)	2 / 500 (0.40%)
occurrences (all)	3	6	4
irritable bowel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
mouth ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	56 / 485 (11.55%)	71 / 486 (14.61%)	29 / 500 (5.80%)
occurrences (all)	69	105	34
paraesthesia oral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	3 / 486 (0.62%)	2 / 500 (0.40%)
occurrences (all)	4	3	3
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	0 / 500 (0.00%)
occurrences (all)	0	2	0
vomiting			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	13 / 485 (2.68%)	18 / 486 (3.70%)	11 / 500 (2.20%)
occurrences (all)	14	22	13
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
cold sweat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	3 / 486 (0.62%)	0 / 500 (0.00%)
occurrences (all)	1	3	0
erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	2
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	3 / 486 (0.62%)	4 / 500 (0.80%)
occurrences (all)	4	4	5
night sweats			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	3	0	1
rash			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
skin burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
skin lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
bladder irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
chromaturia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
pollakiuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
renal pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	2 / 486 (0.41%)	3 / 500 (0.60%)
occurrences (all)	0	2	3
axillary mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	3 / 486 (0.62%)	3 / 500 (0.60%)
occurrences (all)	2	3	3
bone pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
bursitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
costochondritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
groin pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
joint stiffness			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
limb discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 485 (1.65%)	8 / 486 (1.65%)	2 / 500 (0.40%)
occurrences (all)	12	11	2
mobility decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
muscle fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 485 (0.82%)	7 / 486 (1.44%)	4 / 500 (0.80%)
occurrences (all)	5	7	4
muscle tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
muscle twitching			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	6 / 486 (1.23%)	1 / 500 (0.20%)
occurrences (all)	5	9	1
muscular weakness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	23 / 485 (4.74%)	29 / 486 (5.97%)	2 / 500 (0.40%)
occurrences (all)	36	45	3

myalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	2	1	0
musculoskeletal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
musculoskeletal stiffness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	2	0	1
neck pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 485 (0.41%)	3 / 486 (0.62%)	4 / 500 (0.80%)
occurrences (all)	2	3	4
osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	3 / 486 (0.62%)	0 / 500 (0.00%)
occurrences (all)	1	4	0
pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[17]	1 / 403 (0.25%)	1 / 418 (0.24%)	0 / 416 (0.00%)
occurrences (all)	1	1	0
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
diverticulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
ear infection			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
febrile infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
gastroenteritis viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
gastroenteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	1 / 500 (0.20%)
occurrences (all)	0	1	1
influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	5 / 486 (1.03%)	2 / 500 (0.40%)
occurrences (all)	0	5	2
kidney infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	2 / 500 (0.40%)
occurrences (all)	0	0	2
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0

nasopharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 485 (1.65%)	8 / 486 (1.65%)	9 / 500 (1.80%)
occurrences (all)	8	8	9
oral herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	3 / 500 (0.60%)
occurrences (all)	0	0	3
otitis externa			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
periodontitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
pulpitis dental			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 485 (0.62%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	3	0	0
skin infection			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
tonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 485 (1.44%)	2 / 486 (0.41%)	4 / 500 (0.80%)
occurrences (all)	7	2	4
urinary tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	1	1	0
viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 485 (0.21%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	4 / 485 (0.82%)	3 / 486 (0.62%)	0 / 500 (0.00%)
occurrences (all)	4	4	0
food craving			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
hypoglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	1 / 500 (0.20%)
occurrences (all)	0	0	1
increased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	1 / 486 (0.21%)	0 / 500 (0.00%)
occurrences (all)	0	1	0
lactose intolerance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 485 (0.00%)	0 / 486 (0.00%)	0 / 500 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	100 mg Lasmiditan - MEE	200 mg Lasmiditan - MEE	MEE - Control
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 55 (56.36%)	40 / 53 (75.47%)	16 / 54 (29.63%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
lipoma of breast			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
peripheral coldness			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
poor peripheral circulation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
antibiotic prophylaxis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tooth restoration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 55 (14.55%)	9 / 53 (16.98%)	2 / 54 (3.70%)
occurrences (all)	10	13	2
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	1 / 54 (1.85%)
occurrences (all)	0	2	1
chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
chills			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 55 (5.45%)	4 / 53 (7.55%)	2 / 54 (3.70%)
occurrences (all)	4	6	2
feeling abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
feeling cold			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
feeling drunk			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
feeling hot			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
feeling of body temperature change			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
feeling of relaxation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
gait disturbance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
general physical health deterioration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hunger			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
illness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 55 (3.64%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	2	0	0
sense of oppression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
sensation of foreign body			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
sensation of blood flow			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
swelling face			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
thirst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
cervix inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[8]	0 / 55 (0.00%)	0 / 53 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
dysmenorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
endometriosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[10]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
erection increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
intermenstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[12]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[13]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
menstrual disorder			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed[14]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pelvic pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
polymenorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[15]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[16]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dry throat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dysphonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	1 / 54 (1.85%)
occurrences (all)	0	3	1
epistaxis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
hyperventilation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
mouth breathing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
rhinalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
sinus congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

sinonasal obstruction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
sinus pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tachypnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
yawning			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
abnormal dreams			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
aggression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
agitation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	1	1	0
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
apathy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
bradyphrenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
confusional state			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
daydreaming			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	0 / 54 (0.00%)
occurrences (all)	0	3	0
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
depressive symptom			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
derealisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

disorganised speech			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dissociation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
disorientation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dyssomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
emotional disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
emotional distress			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
euphoric mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
fear			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hallucination			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hallucination, auditory			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hallucination, visual			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypnagogic hallucination			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
mood altered			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
nervousness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
nightmare			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0

poor quality sleep			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
psychomotor retardation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
rapid eye movements sleep abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
sleep disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	2	0
somatic symptom disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
suicidal ideation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Investigations			
blood cholesterol increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
blood creatinine increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
blood folate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
blood pressure decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
body temperature increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
electrocardiogram t wave abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
heart rate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
heart rate increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
heart rate irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
intraocular pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscle strength abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pulse abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
total bile acids increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
accidental overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
eye contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscle rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
soft tissue injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
bradycardia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
cardiovascular disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	4 / 53 (7.55%)	0 / 54 (0.00%)
occurrences (all)	0	5	0
supraventricular extrasystoles			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
supraventricular tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
ageusia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
allodynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
altered state of consciousness			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
amnesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
anosmia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
aphasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
ataxia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
aura			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
balance disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	0 / 54 (0.00%)
occurrences (all)	0	3	0
bradykinesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
clumsiness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
cognitive disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
coordination abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	0 / 54 (0.00%)
occurrences (all)	0	2	0
depressed level of consciousness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	24 / 55 (43.64%)	31 / 53 (58.49%)	6 / 54 (11.11%)
occurrences (all)	41	61	8
dizziness postural			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dysaesthesia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dysarthria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dyskinesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dysstasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
fine motor skill dysfunction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
formication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
head discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	2 / 54 (3.70%)
occurrences (all)	0	0	3
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

hemiparesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypersomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 55 (5.45%)	1 / 53 (1.89%)	1 / 54 (1.85%)
occurrences (all)	6	2	4
hypotonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
lethargy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
memory impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
mental impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
migraine with aura			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscle contractions involuntary			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscle spasticity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
myoclonus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	3 / 53 (5.66%)	0 / 54 (0.00%)
occurrences (all)	0	7	0
presyncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
psychomotor hyperactivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
restless legs syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
sedation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
sensorimotor disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
sensory disturbance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
sensory loss			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
serotonin syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
slow speech			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 55 (9.09%)	10 / 53 (18.87%)	1 / 54 (1.85%)
occurrences (all)	7	13	2
speech disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
taste disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
microcytic anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
acute vestibular syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
conductive deafness			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
deafness transitory			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hyperacusis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
motion sickness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	4 / 53 (7.55%)	0 / 54 (0.00%)
occurrences (all)	0	7	0
vertigo positional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
abnormal sensation in eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
blepharospasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
diplopia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
eye movement disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
eyelid ptosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
eyelid skin dryness			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
metamorphopsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
mydriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
ocular discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
photophobia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
photopsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pupillary reflex impaired			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0

visual field defect			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
visual impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
vitreous haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
abdominal discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	2 / 54 (3.70%)
occurrences (all)	0	0	5
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
colitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
dry mouth			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
epigastric discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
glossodynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia oral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

irritable bowel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
mouth ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 55 (10.91%)	4 / 53 (7.55%)	4 / 54 (7.41%)
occurrences (all)	7	6	7
paraesthesia oral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	3 / 53 (5.66%)	1 / 54 (1.85%)
occurrences (all)	0	4	1
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
cold sweat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
erythema			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
night sweats			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
skin burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
skin lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
bladder irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
chromaturia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
renal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
axillary mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
bone pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
groin pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
joint stiffness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
limb discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
mobility decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscle fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

muscle spasms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscle twitching			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 55 (10.91%)	7 / 53 (13.21%)	1 / 54 (1.85%)
occurrences (all)	12	10	1
myalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[17]	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
febrile infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
kidney infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	1 / 54 (1.85%)
occurrences (all)	1	1	1
urinary tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
food craving			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
hypoglycaemia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
increased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
lactose intolerance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 55 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Open Label Extension		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	326 / 477 (68.34%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
lipoma of breast			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 477 (0.00%)		
occurrences (all)	0		
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	2		
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
hot flush			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 477 (1.26%)		
occurrences (all)	10		
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
peripheral coldness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
poor peripheral circulation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
raynaud's phenomenon			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
antibiotic prophylaxis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
tooth restoration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	26 / 477 (5.45%)		
occurrences (all)	60		
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 477 (0.63%)		
occurrences (all)	6		
chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 477 (1.68%)		
occurrences (all)	19		
discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 477 (1.26%)		
occurrences (all)	15		
fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	65 / 477 (13.63%)		
occurrences (all)	241		
feeling abnormal			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	10			
feeling cold				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
feeling drunk				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	4			
feeling hot				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	10			
feeling of body temperature change				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
feeling of relaxation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	46			
gait disturbance				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	5			
general physical health deterioration				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
hunger				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			

illness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
influenza like illness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
malaise				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	8			
non-cardiac chest pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
oedema peripheral				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	4 / 477 (0.84%)			
occurrences (all)	5			
peripheral swelling				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
pyrexia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	7			
sense of oppression				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
sensation of foreign body			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
sensation of blood flow			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
swelling face			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
thirst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
seasonal allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	2		
Reproductive system and breast disorders			
cervix inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[8]	0 / 477 (0.00%)		
occurrences (all)	0		
dysmenorrhoea			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[9]	2 / 413 (0.48%)			
occurrences (all)	2			
endometriosis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[10]	1 / 413 (0.24%)			
occurrences (all)	1			
erection increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[11]	0 / 477 (0.00%)			
occurrences (all)	0			
intermenstrual bleeding				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[12]	0 / 477 (0.00%)			
occurrences (all)	0			
menstruation irregular				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[13]	0 / 477 (0.00%)			
occurrences (all)	0			
menstrual disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[14]	1 / 413 (0.24%)			
occurrences (all)	1			
pelvic pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
polymenorrhoea				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[15]	0 / 477 (0.00%)			
occurrences (all)	0			
vaginal haemorrhage				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed[16]	1 / 413 (0.24%)			
occurrences (all)	1			

Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	2		
dry throat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
dysphonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 477 (1.26%)		
occurrences (all)	16		
epistaxis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
hyperventilation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
mouth breathing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
nasal congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
oropharyngeal pain			
alternative dictionary used:			

MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	5			
rhinalgia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
rhinorrhoea				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
rhinitis allergic				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
sinus congestion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
sinonasal obstruction				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
sinus pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
tachypnoea				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
yawning				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	2		
Psychiatric disorders			
abnormal dreams			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 477 (1.89%)		
occurrences (all)	32		
aggression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
agitation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	3		
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	20 / 477 (4.19%)		
occurrences (all)	47		
apathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
bradyphrenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
confusional state			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	5			
daydreaming				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
depressed mood				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	6 / 477 (1.26%)			
occurrences (all)	18			
depression				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	4 / 477 (0.84%)			
occurrences (all)	10			
depressive symptom				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
derealisation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
disorganised speech				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
dissociation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	4			
disorientation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	8 / 477 (1.68%)			
occurrences (all)	17			

dyssomnia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
emotional disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
emotional distress				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
euphoric mood				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
fear				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
hallucination				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	3			
hallucination, auditory				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
hallucination, visual				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
hypnagogic hallucination				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
insomnia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	15 / 477 (3.14%)			
occurrences (all)	37			
irritability				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	3			
mood altered				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
nervousness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
nightmare				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	15			
poor quality sleep				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	3			
psychomotor retardation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	2			
rapid eye movements sleep abnormal				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			

restlessness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 477 (0.84%)		
occurrences (all)	6		
sleep disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 477 (1.26%)		
occurrences (all)	6		
somatic symptom disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
suicidal ideation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
Investigations			
blood cholesterol increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
blood creatinine increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
blood folate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
blood pressure increased			
alternative dictionary used:			

MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
blood pressure decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
body temperature increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	3			
blood uric acid increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
electrocardiogram t wave abnormal				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
gamma-glutamyltransferase increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
heart rate decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
heart rate increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
heart rate irregular				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
intraocular pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
liver function test abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
muscle strength abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
pulse abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
total bile acids increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
accidental overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 477 (1.05%)		
occurrences (all)	14		
contusion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
epicondylitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
eye contusion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
fall				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
joint dislocation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
joint injury				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
ligament sprain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
limb injury				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
muscle rupture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			

overdose				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
rib fracture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
skin abrasion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
skin laceration				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
soft tissue injury				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
Cardiac disorders				
bradycardia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
cardiovascular disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
palpitations				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	9 / 477 (1.89%)			
occurrences (all)	17			
supraventricular extrasystoles				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
supraventricular tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 477 (1.05%)		
occurrences (all)	8		
Nervous system disorders			
ageusia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
allodynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
altered state of consciousness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
amnesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
anosmia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
aphasia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
ataxia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	3			
aura				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
autonomic nervous system imbalance				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
balance disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	16 / 477 (3.35%)			
occurrences (all)	43			
bradykinesia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
burning sensation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
clumsiness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
cognitive disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			

coordination abnormal				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	9			
depressed level of consciousness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
disturbance in attention				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	6			
dizziness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	159 / 477 (33.33%)			
occurrences (all)	770			
dizziness postural				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
dysaesthesia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
dysarthria				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	7			
dysgeusia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
dyskinesia				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
dysstasia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
fine motor skill dysfunction				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
formication				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
head discomfort				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	20			
headache				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	18 / 477 (3.77%)			
occurrences (all)	49			
hemiparesis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
hypersomnia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	3			
hypoaesthesia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	15 / 477 (3.14%)			
occurrences (all)	30			

hypotonia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
lethargy				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	9 / 477 (1.89%)			
occurrences (all)	11			
memory impairment				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
mental impairment				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
migraine				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	8			
migraine with aura				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
muscle contractions involuntary				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
muscle spasticity				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
myoclonus				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
paraesthesia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	72 / 477 (15.09%)			
occurrences (all)	386			
presyncope				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	11			
psychomotor hyperactivity				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
restless legs syndrome				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	10 / 477 (2.10%)			
occurrences (all)	40			
sedation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
sciatica				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
sensorimotor disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	2			
sensory disturbance				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	4			

sensory loss				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
serotonin syndrome				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
slow speech				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
somnolence				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	49 / 477 (10.27%)			
occurrences (all)	202			
speech disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	4			
syncope				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	4 / 477 (0.84%)			
occurrences (all)	4			
taste disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
tension headache				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
tremor				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	16 / 477 (3.35%)		
occurrences (all)	47		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
microcytic anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
Ear and labyrinth disorders			
acute vestibular syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
conductive deafness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
deafness transitory			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
ear pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
hyperacusis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
motion sickness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	3		
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 477 (1.68%)		
occurrences (all)	17		
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	51 / 477 (10.69%)		
occurrences (all)	211		
vertigo positional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
Eye disorders			
abnormal sensation in eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
blepharospasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
cataract			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
diplopia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	7			
eye movement disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
eye pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
eye pruritus				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
eyelid ptosis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
eyelid skin dryness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	2			
metamorphopsia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
mydriasis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			

ocular discomfort				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
ocular hyperaemia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
photophobia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
photopsia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	7 / 477 (1.47%)			
occurrences (all)	10			
pupillary reflex impaired				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
vision blurred				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	6 / 477 (1.26%)			
occurrences (all)	20			
visual field defect				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
visual impairment				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	5			
vitreous haemorrhage				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
abdominal discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 477 (0.63%)		
occurrences (all)	4		
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	2		
colitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	2		
diarrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 477 (1.89%)		
occurrences (all)	58		
dry mouth			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	3		
dyspepsia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	4 / 477 (0.84%)			
occurrences (all)	6			
epigastric discomfort				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
flatulence				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
gastritis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	3			
gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	5			
glossodynia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
hypoaesthesia oral				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	3			
irritable bowel syndrome				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
mouth ulceration				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			

nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	60 / 477 (12.58%)		
occurrences (all)	153		
paraesthesia oral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 477 (1.47%)		
occurrences (all)	14		
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 477 (1.05%)		
occurrences (all)	5		
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	21 / 477 (4.40%)		
occurrences (all)	27		
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
cold sweat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	3		
night sweats			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	3		
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	2		
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	2		
skin burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
skin lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
Renal and urinary disorders			
bladder irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
chromaturia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
pollakiuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
renal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 477 (0.84%)		
occurrences (all)	4		
axillary mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 477 (1.47%)		
occurrences (all)	7		
bone pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
bursitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
costochondritis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
groin pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	2			
joint stiffness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
limb discomfort				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	12 / 477 (2.52%)			
occurrences (all)	74			
mobility decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
muscle fatigue				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
muscle spasms				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	6 / 477 (1.26%)			
occurrences (all)	17			
muscle tightness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			

musculoskeletal chest pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
muscle twitching				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	7 / 477 (1.47%)			
occurrences (all)	15			
muscular weakness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	11 / 477 (2.31%)			
occurrences (all)	39			
myalgia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	4 / 477 (0.84%)			
occurrences (all)	9			
musculoskeletal pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
musculoskeletal stiffness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
neck pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	5 / 477 (1.05%)			
occurrences (all)	6			
osteoarthritis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
pain in extremity				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	2 / 477 (0.42%)		
occurrences (all)	3		
pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
plantar fasciitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	4		
synovial cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
bacterial vaginosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[17]	0 / 477 (0.00%)		
occurrences (all)	0		
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
covid-19			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	4 / 477 (0.84%)			
occurrences (all)	4			
cystitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
diverticulitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
ear infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
febrile infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
gastroenteritis viral				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
gastroenteritis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
influenza				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
kidney infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	3			

laryngitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
localised infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
lower respiratory tract infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
nasopharyngitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	3			
oral herpes				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
otitis externa				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
periodontitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
pharyngitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
pulpitis dental				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
respiratory tract infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	2 / 477 (0.42%)			
occurrences (all)	2			
rhinitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
skin infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 477 (0.00%)			
occurrences (all)	0			
tonsillitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
tooth abscess				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
tooth infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 477 (0.21%)			
occurrences (all)	1			
upper respiratory tract infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	3 / 477 (0.63%)			
occurrences (all)	3			
urinary tract infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	8 / 477 (1.68%)			
occurrences (all)	8			

viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 477 (0.63%)		
occurrences (all)	3		
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 477 (0.63%)		
occurrences (all)	3		
food craving			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
hyperuricaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
hypoglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
increased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 477 (0.00%)		
occurrences (all)	0		
lactose intolerance			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 477 (0.21%)		
occurrences (all)	1		
type 2 diabetes mellitus alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 477 (0.63%)		
occurrences (all)	3		

Notes:

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 May 2018	Amendment (a): Changes in design of the trial (options for second dose and related secondary objectives were removed), Change of an exclusion criterion (removal of exclusion criteria #17: exclusion of patients with hepatitis/HIV).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported