Clinical trial results:
A Study of Three Doses of Lasmiditan (50 mg, 100 mg and 200 mg) Compared to Placebo in the Acute Treatment of Migraine: A Randomized, Double-blind, Placebo-controlled Parallel Group Study (SPARTAN)

Summary

EudraCT number	2015-005689-40
Trial protocol	GB DE
Global end of trial date	30 June 2017

Results information

Result version number	v1 (current)
This version publication date	15 July 2018
First version publication date	15 July 2018

Trial information

Trial identification

Sponsor protocol code	H8H-CD-LAHK

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02605174
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16889

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-CTLILLY, ClinicalTrials.gov@lilly.com
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877-285-4559, ClinicalTrials.gov@lilly.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 June 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 June 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Participants will be asked to treat a migraine attack with study drug on an outpatient basis. Participants will be provided with a dosing card containing a dose for initial treatment and a second dose to be used for rescue or recurrence of migraine. Each participant's study participation will consist of screening with a telephone contact within 7 days to confirm eligibility, a Treatment Period of up to 8 weeks, and End-of-Study (EoS) within one week (7 days) of treating a single migraine attack. The total time on study is approximately up to 11 weeks.

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	01 May 2016
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	Germany: 310
Country: Number of subjects enrolled	United Kingdom: 191
Country: Number of subjects enrolled	United States: 2504
Worldwide total number of subjects	3005
EEA total number of subjects	501

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)	2855
From 65 to 84 years	150
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Entered

Pre-assignment

Screening details:

Participants were randomly assigned to 1 of 7 sequences and received lasmiditan 50 mg (L50 mg), lasmiditan 100 mg (L100 mg) or lasmiditan 200 mg (L200 mg) or placebo (P) for the first dose and the second dose, if needed for rescue or recurrence of migraine.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Lasmiditan 50 milligram (mg)/Lasmiditan 50 mg

Arm description:

Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

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

Dosage and administration details:

Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm title	Lasmiditan 50 mg/Placebo

Arm description:

Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

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

Dosage and administration details:

Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm title	Lasmiditan 100 mg/Lasmiditan 100 mg

Arm description:

Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm type	Experimental

Investigational medicinal product name	Lasmiditan 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm title	Lasmitidan 100 mg/Placebo

Arm description:

Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

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

Dosage and administration details:

Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm title	Lasmiditan 200 mg/Lasmiditan 200 mg

Arm description:

Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm title	Lasmitidan 200 mg/Placebo

Arm description:

Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

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

Dosage and administration details:

Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm title	Placebo/Placebo

Arm description:

Placebo tablets match each of the lasmiditan doses (50 mg, 100 mg and 200 mg) was administered orally, daily for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Arm type	Placebo

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

Dosage and administration details:

Placebo tablets match each of the lasmiditan doses (50 mg, 100 mg and 200 mg) was administered orally, daily for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Number of subjects in period 1	Lasmiditan 50 milligram (mg)/Lasmiditan 50	Lasmiditan 50 mg/Placebo	Lasmiditan 100 mg/Lasmiditan 100 mg
Started	501	249	502
Received at Least 1 Dose of Study Drug	429 [1]	225 [2]	423 [3]
Received Optional 2nd Dose	206 [4]	96 [5]	177 [6]
Completed	437	226	426
Not completed	64	23	76
Consent withdrawn by subject	9	6	14
Physician decision	2	-	-
Adverse event, non-fatal	-	-	1
Pregnancy	1	-	-
Randomization Failure	22	6	20
Lost to follow-up	20	7	27
Protocol deviation	10	4	14

Number of subjects in period 1	Lasmitidan 100 mg/Placebo	Lasmiditan 200 mg/Lasmiditan 200 mg	Lasmitidan 200 mg/Placebo
Started	252	501	249
Received at Least 1 Dose of Study Drug	212 [7]	434 [8]	215 [9]
Received Optional 2nd Dose	83 [10]	144 [11]	74 [12]
Completed	216	448	217
Not completed	36	53	32
Consent withdrawn by subject	11	6	4
Physician decision	-	-	-
Adverse event, non-fatal	-	4	-
Pregnancy	2	-	-
Randomization Failure	7	16	11
Lost to follow-up	10	20	10
Protocol deviation	6	7	7

Number of subjects in period 1	Placebo/Placebo
Started	751

Received at Least 1 Dose of Study Drug	645 [13]
Received Optional 2nd Dose	361 [14]
Completed	662
Not completed	89
Consent withdrawn by subject	15
Physician decision	3
Adverse event, non-fatal	-
Pregnancy	-
Randomization Failure	30
Lost to follow-up	29
Protocol deviation	12

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those

participants who started the study.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.
[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: One site was burned down and several participants have incomplete data.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.
[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.
[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.
[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.
[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants who completed the study was adjusted due to one site which burned down and therefore several participants have incomplete data. All participants who received at least one dose of study drug and all participants who received a 2nd dose are subset to those participants who started the study.

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study
Reporting group description:	
All randomized participants who received at least one dose of study drug.	

Reporting group values	Overall Study	Total	
Number of subjects	3005	3005	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	2855	2855	
From 65-84 years	150	150	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	42.3		
standard deviation	± 12.93	-	
Gender categorical Units: Subjects			
Female	2515	2515	
Male	490	490	
Race/Ethnicity, Customized			
Race at baseline			
Units: Subjects			
American Indian or Alaska Native	18	18	
Asian	26	26	
Black or African American	522	522	
Native Hawaiian or other Pacific Islander	11	11	
White	2370	2370	
Other	28	28	
Multiple	23	23	
Missing	7	7	
Race/Ethnicity, Customized			
Ethnicity at baseline			
Units: Subjects			
Hispanic or Latino	610	610	
Not Hispanic or Latino	2373	2373	
Not Reported	10	10	
Unknown	5	5	
Missing	7	7	

Region of Enrollment Units: Subjects			
Germany	310	310	
United Kingdom	191	191	
United States	2504	2504	

End points

End points reporting groups

Reporting group title	Lasmiditan 50 milligram (mg)/Lasmiditan 50 mg
Reporting group description:	
Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.	
Reporting group title	Lasmiditan 50 mg/Placebo
Reporting group description:	
Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.	
Reporting group title	Lasmiditan 100 mg/Lasmiditan 100 mg
Reporting group description:	
Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.	
Reporting group title	Lasmitidan 100 mg/Placebo
Reporting group description:	
Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.	
Reporting group title	Lasmiditan 200 mg/Lasmiditan 200 mg
Reporting group description:	
Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.	
Reporting group title	Lasmitidan 200 mg/Placebo
Reporting group description:	
Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.	
Reporting group title	Placebo/Placebo
Reporting group description:	
Placebo tablets match each of the lasmiditan doses (50 mg, 100 mg and 200 mg) was administered orally, daily for acute treatment of migraine. An optional second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.	
Subject analysis set title	Lasmiditan 50 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
All randomized participants who received at least one dose of study drug, had evaluable headache pain free data and were treated for a qualifying migraine within 4 hours of onset.	
Subject analysis set title	Lasmiditan 100 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
All randomized participants who received at least one dose of study drug, had evaluable headache pain free data and were treated for a qualifying migraine within 4 hours of onset.	
Subject analysis set title	Lasmiditan 200 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
All randomized participants who received at least one dose of study drug, had evaluable headache pain free data and were treated for a qualifying migraine within 4 hours of onset.	
Subject analysis set title	Placebo
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
All randomized participants who received at least one dose of study drug, had evaluable headache pain free data and were treated for a qualifying migraine within 4 hours of onset.	
Subject analysis set title	Lasmiditan 50 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug, had evaluable most bothersome symptoms (MBS) data and were treated for a qualifying migraine within 4 hours of onset.

Subject analysis set title	Lasmiditan 100 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug, had evaluable MBS data and were treated for a qualifying migraine within 4 hours of onset.

Subject analysis set title	Lasmiditan 200 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug, had evaluable MBS data and were treated for a qualifying migraine within 4 hours of onset.

Subject analysis set title	Placebo
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug, had evaluable MBS data and were treated for a qualifying migraine within 4 hours of onset.

Subject analysis set title	Lasmiditan 50 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

Subject analysis set title	Lasmiditan 100 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

Subject analysis set title	Lasmiditan 200 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

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

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

Subject analysis set title	Lasmiditan 50 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

Subject analysis set title	Lasmiditan 100 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

Subject analysis set title	Lasmiditan 200 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

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

Subject analysis set description:

All randomized participants who received at least one dose of study drug and had evaluable post-dose headache severity or symptom assessments.

Subject analysis set title	Lasmiditan 50 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

All randomized participants who received study drug (first dose).

Subject analysis set title	Lasmiditan 100 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

All randomized participants who received study drug (first dose).

Subject analysis set title	Lasmiditan 200 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

All randomized participants who received study drug (first dose).

Subject analysis set title	Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

All randomized participants who received study drug (first dose).

Primary: Percentage of Participants Headache Pain Free at 2 Hours Post Dose

End point title	Percentage of Participants Headache Pain Free at 2 Hours Post Dose

End point description:

The percentage of participants defined as mild, moderate, or severe headache pain becoming none.

End point type	Primary

End point timeframe:

2 hours post dose

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	556[1]	532[2]	528[3]	539[4]
Units: percentage of participants				
number (not applicable)	29	31	39	21

Notes:

[1] - All intent to treat (ITT) participants who treated a qualifying migraine within 4 hours of onset.

[2] - All ITT participants who treated a qualifying migraine within 4 hours of onset.

[3] - All ITT participants who treated a qualifying migraine within 4 hours of onset.

[4] - All ITT participants who treated a qualifying migraine within 4 hours of onset.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg

Statistical analysis description:

Statistical analysis for Lasmiditan 200 mg compared with placebo

Comparison groups	Placebo v Lasmiditan 200 mg

Number of subjects included in analysis	1067
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	3.1

Statistical analysis title	Lasmiditan 100 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 100 mg compared with placebo	
Comparison groups	Lasmiditan 100 mg v Placebo
Number of subjects included in analysis	1071
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	2.2

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1095
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.9

Primary: Percentage of participants who are most bothersome symptom (MBS) free	
End point title	Percentage of participants who are most bothersome symptom (MBS) free

End point description:

The percentage of participants defined as the associated symptom present and identified as MBS (nausea, photophobia, or phonophobia) prior to dosing being absent.

End point type	Primary

End point timeframe:

2 hours post dose

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	512[5]	500[6]	483[7]	514[8]
Units: percentage of participants				
number (not applicable)	41	44	49	33

Notes:

[5] - All ITT participants who treated a qualifying migraine within 4 hours of onset.

[6] - All ITT participants who treated a qualifying migraine within 4 hours of onset.

[7] - All ITT participants who treated a qualifying migraine within 4 hours of onset.

[8] - All ITT participants who treated a qualifying migraine within 4 hours of onset.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg

Statistical analysis description:

Statistical analysis for Lasmiditan 200 mg compared with placebo

Comparison groups	Placebo v Lasmiditan 200 mg
Number of subjects included in analysis	997
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	2.4

Statistical analysis title	Lasmiditan 100 mg

Statistical analysis description:

Statistical analysis for Lasmiditan 100 mg compared with placebo

Comparison groups	Lasmiditan 100 mg v Placebo
Number of subjects included in analysis	1014
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	2

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.8

Other pre-specified: Percentage of Participants with Headache relief

End point title	Percentage of Participants with Headache relief
End point description:	
The percentage of participants with headache pain moderate or severe which became mild or none or with headache pain mild which became none.	
End point type	Other pre-specified
End point timeframe:	
2 hours post dose	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	598[9]	571[10]	565[11]	576[12]
Units: percentage of participants				
number (not applicable)	59	65	65	48

Notes:

[9] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[10] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[11] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[12] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 200 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 200 mg
Number of subjects included in analysis	1141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	3.1

Statistical analysis title	Lasmiditan 100 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 100 mg compared with placebo	
Comparison groups	Lasmiditan 100 mg v Placebo
Number of subjects included in analysis	1147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.7
upper limit	2.9

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	2.2

Other pre-specified: Number of Participants with Headache Recurrence	
End point title	Number of Participants with Headache Recurrence
End point description:	
The number of participants with headache recurrence (moderate or severe at baseline which became pain-free at 2 hours post dose and worsened again up to 48 hours post dose)	
End point type	Other pre-specified
End point timeframe:	
From 2 Hours Post Dose Up to 48 Hours	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	159[13]	167[14]	205[15]	115[16]
Units: Participants				
number (not applicable)	38	44	52	26

Notes:

[13] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[14] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[15] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[16] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Participants Use of rescue medication	
End point title	Percentage of Participants Use of rescue medication
End point description:	
The percentage of participants who used rescue medication.	
End point type	Other pre-specified
End point timeframe:	
2 hours post dose	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	598[17]	571[18]	565[19]	576[20]
Units: percentage of participants				
number (not applicable)	32	26	19	41

Notes:

[17] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[18] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[19] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[20] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 200 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 200 mg
Number of subjects included in analysis	1141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	0.4

Statistical analysis title	Lasmiditan 100 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 100 mg compared with placebo	
Comparison groups	Lasmiditan 100 mg v Placebo

Number of subjects included in analysis	1147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.7

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.9

Other pre-specified: Percentage of Participants Use of rescue medication	
End point title	Percentage of Participants Use of rescue medication
End point description:	
The percentage of participants who used rescue medication.	
End point type	Other pre-specified
End point timeframe:	
From 2 Hours Post Dose Up to 24 Hours	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	598[21]	571[22]	565[23]	576[24]
Units: percentage of participants				
number (not applicable)	9	6	7	9

Notes:

[21] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[22] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[23] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[24] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 200 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 200 mg
Number of subjects included in analysis	1141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.456
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.3

Statistical analysis title	Lasmiditan 100 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 100 mg compared with placebo	
Comparison groups	Lasmiditan 100 mg v Placebo
Number of subjects included in analysis	1147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.129
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.1

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.917
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.5

Other pre-specified: Percentage of Participants Use of rescue medication	
End point title	Percentage of Participants Use of rescue medication
End point description:	
The percentage of participants who used rescue medication.	
End point type	Other pre-specified
End point timeframe:	
From 24 Post Dose Up to 48 Hours	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	598[25]	571[26]	565[27]	576[28]
Units: percentage of participants				
number (not applicable)	0	0	0	0

Notes:

[25] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[26] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[27] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[28] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of participants nausea free	
End point title	Percentage of participants nausea free
End point description: The percentage of participant without nausea.	
End point type	Other pre-specified
End point timeframe: 2 hours post dose	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	598[29]	571[30]	565[31]	576[32]
Units: percentage of participants				
number (not applicable)	69	72	70	70

Notes:

[29] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[30] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[31] - All randomized participants received at least one dose of study drug and evaluable post-dose data.
[32] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg
Statistical analysis description: Statistical analysis for Lasmiditan 200 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 200 mg
Number of subjects included in analysis	1141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.992
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.3

Statistical analysis title	Lasmiditan 100 mg
Statistical analysis description: Statistical analysis for Lasmiditan 100 mg compared with placebo	
Comparison groups	Lasmiditan 100 mg v Placebo

Number of subjects included in analysis	1147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.622
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.4

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.522
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.2

Other pre-specified: Percentage of participants with phonophobia free	
End point title	Percentage of participants with phonophobia free
End point description:	
The percentage of participants without phonophobia.	
End point type	Other pre-specified
End point timeframe:	
2 hours post dose	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	598[33]	571[34]	565[35]	576[36]
Units: percentage of participants				
number (not applicable)	61	65	65	53

Notes:

[33] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[34] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[35] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[36] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 200 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 200 mg
Number of subjects included in analysis	1141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	2.1

Statistical analysis title	Lasmiditan 100 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 100 mg compared with placebo	
Comparison groups	Lasmiditan 100 mg v Placebo
Number of subjects included in analysis	1147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	2

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.7

Other pre-specified: Percentage of participants with photophobia free	
End point title	Percentage of participants with photophobia free
End point description:	
The percentage of participants without photophobia.	
End point type	Other pre-specified
End point timeframe:	
2 hours post dose	

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	598[37]	571[38]	565[39]	576[40]
Units: percentage of participants				
number (not applicable)	51	56	58	43

Notes:

[37] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[38] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[39] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

[40] - All randomized participants received at least one dose of study drug and evaluable post-dose data.

Statistical analyses

Statistical analysis title	Lasmiditan 200 mg

Statistical analysis description:	
Statistical analysis for Lasmiditan 200 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 200 mg
Number of subjects included in analysis	1141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	2.3

Statistical analysis title	Lasmiditan 100 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 100 mg compared with placebo	
Comparison groups	Lasmiditan 100 mg v Placebo
Number of subjects included in analysis	1147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	2.1

Statistical analysis title	Lasmiditan 50 mg
Statistical analysis description:	
Statistical analysis for Lasmiditan 50 mg compared with placebo	
Comparison groups	Placebo v Lasmiditan 50 mg
Number of subjects included in analysis	1174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.7

Other pre-specified: Percentage of Participants with Resource Utilization

End point title	Percentage of Participants with Resource Utilization

End point description:

Use of health care for treatment 6 months prior to enrolling in the study and information reported during time on study

End point type	Other pre-specified

End point timeframe:

6 months prior to enrolling in study to End of Study (within 7 days of treating a single migraine attack)

End point values	Lasmiditan 50 milligram (mg)/Lasmiditan 50 mg	Lasmiditan 50 mg/Placebo	Lasmiditan 100 mg/Lasmiditan 100 mg	Lasmitidan 100 mg/Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	429[41]	225[42]	423[43]	212[44]
Units: percentage of participants				
number (not applicable)				
6 months prior to enrolling	5	2	3	2
During time of study	1	0	1	0

Notes:

[41] - All randomized participants who had received at least one dose of study drug.

[42] - All randomized participants who had received at least one dose of study drug.

[43] - All randomized participants who had received at least one dose of study drug.

[44] - All randomized participants who had received at least one dose of study drug.

End point values	Lasmiditan 200 mg/Lasmiditan 200 mg	Lasmitidan 200 mg/Placebo	Placebo/Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	434[45]	215[46]	645[47]	
Units: percentage of participants				
number (not applicable)				
6 months prior to enrolling	3	3	3	
During time of study	1	1	1	

Notes:

[45] - All randomized participants who had received at least one dose of study drug.

[46] - All randomized participants who had received at least one dose of study drug.

[47] - All randomized participants who had received at least one dose of study drug.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants with Treatment Emergent Events

End point title	Number of Participants with Treatment Emergent Events

End point description:

Safety and Tolerability was assessed by the number of participants with at least 1 TEAE. A summary of other non-serious adverse events and all serious adverse events, regardless of causality, is located in the Reported Adverse Events Section

End point type	Other pre-specified

End point timeframe:

From Baseline Up to End of Study (Up to 11 Weeks)

End point values	Lasmiditan 50 mg	Lasmiditan 100 mg	Lasmiditan 200 mg	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	654[48]	635[49]	649[50]	645[51]
Units: participants				
number (not applicable)	167	230	253	75

Notes:

[48] - All randomized participants who received study drug (first dose).

[49] - All randomized participants who received study drug (first dose).

[50] - All randomized participants who received study drug (first dose).

[51] - All randomized participants who received study drug (first dose).

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

The safety population includes all participants who received at least one dose of study drug and the optional second dose.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Lasmitidan 50 mg; Lasmitidan 50 mg

Reporting group description:

Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional Lasmitidan 50 mg second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Reporting group title	Lasmitidan 50 mg; Placebo

Reporting group description:

Lasmiditan 50 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Reporting group title	Lasmitidan 100 mg; Lasmitidan 100 mg

Reporting group description:

Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional Lasmitidan 100 mg second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Reporting group title	Lasmitidan 100 mg; Placebo

Reporting group description:

Lasmiditan 100 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine

Reporting group title	Lasmitidan 200 mg; Lasmitidan 200 mg

Reporting group description:

Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional Lasmitidan 200 mg second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Reporting group title	Lasmitidan 200 mg; Placebo

Reporting group description:

Lasmiditan 200 mg was administered orally, once for acute treatment of migraine. An optional placebo second dose was administered between 2 and 24 hours for rescue or recurrence of migraine.

Reporting group title	Placebo; Placebo

Reporting group description:

Placebo tablets match each of the lasmiditan doses (50 mg, 100 mg and 200 mg) was administered orally, once for acute treatment of migraine. A second optional dose was administered within 24 hours for rescue or recurrence of migraine.

Serious adverse events	Lasmitidan 50 mg; Lasmitidan 50 mg	Lasmitidan 50 mg; Placebo	Lasmitidan 100 mg; Lasmitidan 100 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	1 / 423 (0.24%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
pituitary tumor benign			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (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
hypotension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (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
Surgical and medical procedures			
surgery			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (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			
presyncope			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (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			
intestinal obstruction			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (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			
cholelithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (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			
somatisation disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (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	Lasmitidan 100 mg; Placebo	Lasmitidan 200 mg; Lasmitidan 200 mg	Lasmitidan 200 mg; Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 212 (0.47%)	3 / 435 (0.69%)	0 / 217 (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)			
pituitary tumor benign			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (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
hypotension			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (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			
surgery			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (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
Nervous system disorders			
presyncope			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (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
Gastrointestinal disorders			
intestinal obstruction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (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			
cholelithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (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			
somatisation disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (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

Serious adverse events	Placebo; Placebo		

Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 646 (0.31%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
pituitary tumor benign			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypotension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
surgery			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
presyncope			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

intestinal obstruction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
somatisation disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Lasmitidan 50 mg; Lasmitidan 50 mg	Lasmitidan 50 mg; Placebo	Lasmitidan 100 mg; Lasmitidan 100 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	118 / 429 (27.51%)	61 / 225 (27.11%)	149 / 423 (35.22%)
Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
flushing			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	2 / 429 (0.47%)	2 / 225 (0.89%)	1 / 423 (0.24%)
occurrences (all)	2	2	1
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	2 / 225 (0.89%)	2 / 423 (0.47%)
occurrences (all)	2	2	2
chest discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	2 / 225 (0.89%)	0 / 423 (0.00%)
occurrences (all)	0	2	0
chills			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
face edema			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	13 / 429 (3.03%)	7 / 225 (3.11%)	13 / 423 (3.07%)
occurrences (all)	13	7	13
feeling abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	2 / 225 (0.89%)	3 / 423 (0.71%)
occurrences (all)	0	2	3
feeling cold			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
feeling hot			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	2 / 423 (0.47%)
occurrences (all)	0	0	2
feeling jittery			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
gait disturbance			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
mass			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1

sense of oppression			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
thirst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	1 / 423 (0.24%)
occurrences (all)	0	1	2
Reproductive system and breast disorders			
menorrhagia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	1 / 351 (0.28%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
ovarian cyst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 357 (0.28%)
occurrences (all)	0	0	1
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	0 / 406 (0.00%)	0 / 224 (0.00%)	1 / 420 (0.24%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
dyspnea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0

epistaxis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
nasal congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
nasal odour			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
paranasal sinus discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
respiratory tract congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
sinus congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
throat tightness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

abnormal dreams			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	3	0	1
adjustment disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
adjustment disorder with anxiety			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	1 / 225 (0.44%)	6 / 423 (1.42%)
occurrences (all)	2	1	6
burnout syndrome			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
confusional state			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
delirium			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
depersonalization			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
depressed mood			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
disorientation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
euphoric mood			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	0 / 225 (0.00%)	5 / 423 (1.18%)
occurrences (all)	2	0	5
hallucination			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
hallucination, visual			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
hypervigilance			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
mental disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
mental status changes			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0

mood swings			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
nightmare			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
panic attack			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
panic reaction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
restlessness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	2 / 225 (0.89%)	2 / 423 (0.47%)
occurrences (all)	0	2	2
sleep disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
sleep terror			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
suicidal ideation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
Investigations			

blood pressure decreased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
heart rate increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
pulse pressure increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
arthropod sting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
contusion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
skin abrasion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
tendon injury			
alternative dictionary used:			

MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 429 (0.70%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	4	0	1
tachycardia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	2 / 423 (0.47%)
occurrences (all)	0	1	2
Nervous system disorders			
aphasia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
ataxia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
aura			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
balance disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	1	0	1
clumsiness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
cognitive disorder			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
coordination abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	39 / 429 (9.09%)	18 / 225 (8.00%)	77 / 423 (18.20%)
occurrences (all)	42	19	84
dysesthesia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
dysarthria			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
facial spasm			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
formication			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	2 / 423 (0.47%)
occurrences (all)	0	0	3

head discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	1 / 225 (0.44%)	1 / 423 (0.24%)
occurrences (all)	1	1	1
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	2	0	1
hypoesthesia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	0 / 225 (0.00%)	5 / 423 (1.18%)
occurrences (all)	2	0	6
lethargy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	7 / 429 (1.63%)	2 / 225 (0.89%)	4 / 423 (0.95%)
occurrences (all)	8	2	4
migraine			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
myoclonus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
paresthesia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	11 / 429 (2.56%)	7 / 225 (3.11%)	21 / 423 (4.96%)
occurrences (all)	13	7	22
presyncope			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
psychomotor hyperactivity			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
sedation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	2 / 423 (0.47%)
occurrences (all)	1	0	2
sensory disturbance			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	24 / 429 (5.59%)	11 / 225 (4.89%)	21 / 423 (4.96%)
occurrences (all)	25	11	21
stupor			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
syncope			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	2	0	0
tremor			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	2 / 423 (0.47%)
occurrences (all)	0	1	2
vertigo cns origin			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
motion sickness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
tinnitus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	1	1	0
vertigo			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	1 / 225 (0.44%)	3 / 423 (0.71%)
occurrences (all)	1	1	3
Eye disorders			
blepharospasm			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
chromatopsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
keratitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
mydriasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
ocular hyperemia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
photopsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
strabismus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
vision blurred			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	1	0	1
visual acuity reduced			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
visual impairment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
vitreous floaters			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	1 / 423 (0.24%)
occurrences (all)	0	1	1
abdominal pain upper			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	2	0	1
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	2
dry mouth			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	3	0	1
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	1	0	1
hypoesthesia oral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
lip dry			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	12 / 429 (2.80%)	6 / 225 (2.67%)	13 / 423 (3.07%)
occurrences (all)	12	6	13
paresthesia oral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0

retching			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
vomiting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	4 / 225 (1.78%)	2 / 423 (0.47%)
occurrences (all)	2	4	2
Skin and subcutaneous tissue disorders			
hyperhidrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	2 / 225 (0.89%)	0 / 423 (0.00%)
occurrences (all)	0	2	0
pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
pruritus generalised			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
urinary incontinence			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
Endocrine disorders			
hyperthyroidism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue			

disorders			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	1	0	1
muscle twitching			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	3 / 423 (0.71%)
occurrences (all)	0	0	3
muscular weakness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	6 / 429 (1.40%)	1 / 225 (0.44%)	4 / 423 (0.95%)
occurrences (all)	6	1	4
musculoskeletal chest pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
musculoskeletal pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	0 / 423 (0.00%)
occurrences (all)	0	1	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
pain in extremity			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 429 (0.23%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	1	0	0
gastroenteritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
hordeolum			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 429 (0.47%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	2	0	0
laryngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
rhinitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 429 (0.70%)	1 / 225 (0.44%)	2 / 423 (0.47%)
occurrences (all)	3	1	2
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	1 / 225 (0.44%)	1 / 423 (0.24%)
occurrences (all)	0	1	1
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	0 / 423 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 429 (0.00%)	0 / 225 (0.00%)	1 / 423 (0.24%)
occurrences (all)	0	0	1

Non-serious adverse events	Lasmitidan 100 mg; Placebo	Lasmitidan 200 mg; Lasmitidan 200 mg	Lasmitidan 200 mg; Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	94 / 212 (44.34%)	177 / 435 (40.69%)	87 / 217 (40.09%)
Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
flushing			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	1 / 435 (0.23%)	1 / 217 (0.46%)
occurrences (all)	1	1	1
hot flush			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 212 (1.89%)	8 / 435 (1.84%)	4 / 217 (1.84%)
occurrences (all)	4	8	4
chest discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	2 / 217 (0.92%)
occurrences (all)	0	0	2
chills			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
face edema			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
fatigue			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	15 / 212 (7.08%)	21 / 435 (4.83%)	12 / 217 (5.53%)
occurrences (all)	15	21	12
feeling abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	4 / 435 (0.92%)	1 / 217 (0.46%)
occurrences (all)	1	4	1
feeling cold			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
feeling hot			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	3 / 435 (0.69%)	0 / 217 (0.00%)
occurrences (all)	0	3	0
feeling jittery			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	2 / 217 (0.92%)
occurrences (all)	0	2	2
gait disturbance			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	1 / 217 (0.46%)
occurrences (all)	0	2	1
malaise			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
mass			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	0 / 217 (0.00%)
occurrences (all)	0	2	0

peripheral swelling			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
sense of oppression			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
thirst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
menorrhagia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	0 / 212 (0.00%)	2 / 364 (0.55%)	0 / 217 (0.00%)
occurrences (all)	0	2	0
ovarian cyst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	0 / 212 (0.00%)	0 / 414 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0

cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
dyspnea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
epistaxis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
nasal odour			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
paranasal sinus discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
respiratory tract congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
abnormal dreams			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
adjustment disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
adjustment disorder with anxiety			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
anxiety			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	3 / 435 (0.69%)	1 / 217 (0.46%)
occurrences (all)	0	3	1
burnout syndrome			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
confusional state			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
delirium			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
depersonalization			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
disorientation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	2 / 217 (0.92%)
occurrences (all)	0	1	2
euphoric mood			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	1 / 217 (0.46%)
occurrences (all)	0	2	1
hallucination			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
hallucination, visual			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	1	1	0
hypervigilance			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
insomnia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	3 / 435 (0.69%)	0 / 217 (0.00%)
occurrences (all)	0	3	0

mental disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
mental status changes			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
mood swings			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
nightmare			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
panic reaction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 212 (1.42%)	3 / 435 (0.69%)	0 / 217 (0.00%)
occurrences (all)	3	3	0
sleep disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
sleep terror			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
suicidal ideation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
Investigations			
blood pressure decreased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
blood pressure increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
heart rate increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	1	1	0
pulse pressure increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
arthropod sting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
tendon injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	1 / 435 (0.23%)	1 / 217 (0.46%)
occurrences (all)	1	1	2
tachycardia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	1 / 217 (0.46%)
occurrences (all)	0	1	1
Nervous system disorders			
aphasia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
ataxia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	0 / 217 (0.00%)
occurrences (all)	0	2	0
aura			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
balance disorder			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	2 / 217 (0.92%)
occurrences (all)	0	2	2
clumsiness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
cognitive disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	0 / 217 (0.00%)
occurrences (all)	0	2	0
coordination abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	2	0	0
disturbance in attention			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
dizziness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	45 / 212 (21.23%)	89 / 435 (20.46%)	33 / 217 (15.21%)
occurrences (all)	45	94	33
dysesthesia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
dysarthria			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	2 / 435 (0.46%)	1 / 217 (0.46%)
occurrences (all)	2	2	1
dysgeusia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0

facial spasm			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
formication			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	2	0	1
head discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	3 / 435 (0.69%)	0 / 217 (0.00%)
occurrences (all)	0	3	0
hypoesthesia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 212 (2.36%)	10 / 435 (2.30%)	0 / 217 (0.00%)
occurrences (all)	5	10	0
lethargy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 212 (1.89%)	7 / 435 (1.61%)	7 / 217 (3.23%)
occurrences (all)	4	7	7
migraine			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
myoclonus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
paresthesia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	17 / 212 (8.02%)	30 / 435 (6.90%)	13 / 217 (5.99%)
occurrences (all)	17	34	14
presyncope			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
psychomotor hyperactivity			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
sedation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	2 / 435 (0.46%)	2 / 217 (0.92%)
occurrences (all)	2	2	2
sensory disturbance			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 212 (1.42%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	3	0	0
somnolence			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	10 / 212 (4.72%)	34 / 435 (7.82%)	12 / 217 (5.53%)
occurrences (all)	10	36	12
stupor			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
syncope			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
tremor			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	4 / 435 (0.92%)	2 / 217 (0.92%)
occurrences (all)	0	4	2

vertigo cns origin			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
motion sickness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
vertigo			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	3 / 435 (0.69%)	2 / 217 (0.92%)
occurrences (all)	3	3	2
Eye disorders			
blepharospasm			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
chromatopsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
keratitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
mydriasis			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
ocular hyperemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
photopsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
strabismus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	2	1	0
visual acuity reduced			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
visual impairment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	2 / 435 (0.46%)	1 / 217 (0.46%)
occurrences (all)	1	2	1
vitreous floaters			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	1	0	1
abdominal pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	2	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	1 / 217 (0.46%)
occurrences (all)	0	1	1
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	1 / 217 (0.46%)
occurrences (all)	0	1	1
dry mouth			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	2 / 435 (0.46%)	1 / 217 (0.46%)
occurrences (all)	1	2	1
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
hypoesthesia oral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
lip dry			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	9 / 212 (4.25%)	14 / 435 (3.22%)	4 / 217 (1.84%)
occurrences (all)	9	14	4

paresthesia oral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	3 / 435 (0.69%)	0 / 217 (0.00%)
occurrences (all)	0	3	0
retching			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	3 / 435 (0.69%)	3 / 217 (1.38%)
occurrences (all)	2	3	3
Skin and subcutaneous tissue disorders			
hyperhidrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
pruritus generalised			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
urinary incontinence			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

hyperthyroidism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	1 / 217 (0.46%)
occurrences (all)	0	2	1
muscle spasms			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
muscle twitching			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	2 / 435 (0.46%)	2 / 217 (0.92%)
occurrences (all)	0	2	2
muscular weakness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 212 (1.89%)	7 / 435 (1.61%)	2 / 217 (0.92%)
occurrences (all)	4	7	2
musculoskeletal chest pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
musculoskeletal pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used:			

MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
myalgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
neck pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
pain in extremity			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	1 / 217 (0.46%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0
rhinitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 212 (0.47%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	1	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 212 (0.94%)	3 / 435 (0.69%)	2 / 217 (0.92%)
occurrences (all)	2	3	2
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	0 / 435 (0.00%)	0 / 217 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 212 (0.00%)	1 / 435 (0.23%)	0 / 217 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Placebo; Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	80 / 646 (12.38%)		

Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
flushing			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 646 (0.31%)		
occurrences (all)	3		
hot flush			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 646 (0.46%)		
occurrences (all)	3		
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
chest discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 646 (0.31%)		
occurrences (all)	2		
chills			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 646 (0.31%)		
occurrences (all)	2		
face edema			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
fatigue			

alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	6 / 646 (0.93%)			
occurrences (all)	6			
feeling abnormal				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	1			
feeling cold				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	1			
feeling hot				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
feeling jittery				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
gait disturbance				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
malaise				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
mass				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
non-cardiac chest pain				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
peripheral swelling			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
sense of oppression			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
thirst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
menorrhagia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	0 / 646 (0.00%)		
occurrences (all)	0		
ovarian cyst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	0 / 646 (0.00%)		
occurrences (all)	0		
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	0 / 633 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
cough				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
dyspnea				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
epistaxis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
nasal congestion				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
nasal odour				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
oropharyngeal pain				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	1			
paranasal sinus discomfort				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
respiratory tract congestion				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			

sinus congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
throat tightness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
Psychiatric disorders			
abnormal dreams			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
adjustment disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
adjustment disorder with anxiety			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
anxiety			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
burnout syndrome			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
confusional state			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
delirium			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
depersonalization				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
depressed mood				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
disorientation				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	1			
euphoric mood				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
hallucination				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
hallucination, visual				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
hypervigilance				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
insomnia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			

mental disorder				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
mental status changes				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
mood swings				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
nightmare				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
panic attack				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
panic reaction				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
restlessness				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
sleep disorder				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
sleep terror				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
suicidal ideation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Investigations			
blood pressure decreased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
blood pressure increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
heart rate increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
pulse pressure increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
arthropod sting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
contusion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
ligament sprain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
skin abrasion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
tendon injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
tachycardia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
aphasia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
ataxia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
aura			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
balance disorder			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
clumsiness				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
cognitive disorder				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
coordination abnormal				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
disturbance in attention				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
dizziness				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	16 / 646 (2.48%)			
occurrences (all)	17			
dysesthesia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
dysarthria				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
dysgeusia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	2 / 646 (0.31%)			
occurrences (all)	2			

facial spasm				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
formication				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
head discomfort				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	1			
headache				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	1			
hypoesthesia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	2 / 646 (0.31%)			
occurrences (all)	2			
lethargy				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	1			
migraine				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
myoclonus				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
paresthesia				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	6 / 646 (0.93%)			
occurrences (all)	6			
presyncope				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
psychomotor hyperactivity				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
sedation				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
sensory disturbance				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
somnolence				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	13 / 646 (2.01%)			
occurrences (all)	13			
stupor				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
syncope				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
tremor				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			

vertigo cns origin			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
motion sickness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
tinnitus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
vertigo			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
Eye disorders			
blepharospasm			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
chromatopsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
keratitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
mydriasis			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
ocular hyperemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
photopsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
strabismus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
vision blurred			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
visual acuity reduced			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
visual impairment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
vitreous floaters			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
abdominal pain				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
abdominal pain upper				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
diarrhoea				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	2			
dry mouth				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	2 / 646 (0.31%)			
occurrences (all)	2			
dyspepsia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
hypoesthesia oral				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
lip dry				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
nausea				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	9 / 646 (1.39%)			
occurrences (all)	9			

paresthesia oral alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) retching alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) toothache alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) vomiting alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	1 / 646 (0.15%) 1 1 / 646 (0.15%) 1 0 / 646 (0.00%) 0 3 / 646 (0.46%) 3		
Skin and subcutaneous tissue disorders hyperhidrosis alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) pruritus alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) pruritus generalised alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	 1 / 646 (0.15%) 1 1 / 646 (0.15%) 1 0 / 646 (0.00%) 0		
Renal and urinary disorders urinary incontinence alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	 0 / 646 (0.00%) 0		
Endocrine disorders			

hyperthyroidism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 646 (0.31%)		
occurrences (all)	2		
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
muscle spasms			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
muscle twitching			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
muscular weakness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
musculoskeletal chest pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
musculoskeletal pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
musculoskeletal stiffness			
alternative dictionary used:			

MedDRA 18.0				
subjects affected / exposed	1 / 646 (0.15%)			
occurrences (all)	2			
myalgia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
neck pain				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
pain in extremity				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
Infections and infestations				
bronchitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
gastroenteritis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
hordeolum				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
influenza				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 646 (0.00%)			
occurrences (all)	0			
laryngitis				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 646 (0.46%)		
occurrences (all)	3		
rhinitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
sinusitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 646 (0.46%)		
occurrences (all)	3		
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 646 (0.15%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 646 (0.00%)		
occurrences (all)	0		

Notes:

[1] - 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 participants exposed has been adjusted accordingly.

[2] - 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 participants exposed has been adjusted accordingly.
[3] - 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 participants exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported