

**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
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**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
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<b>Arm title</b>	Lasmiditan 50 milligram (mg)/Lasmiditan 50 mg
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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.

<b>Arm title</b>	Lasmiditan 50 mg/Placebo
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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.

<b>Arm title</b>	Lasmiditan 100 mg/Lasmiditan 100 mg
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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
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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.	
<b>Arm title</b>	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.	
<b>Arm title</b>	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.	
<b>Arm title</b>	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.	
<b>Arm title</b>	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	Lasmitidan 50 milligram (mg)/Lasmitidan 50	Lasmitidan 50 mg/Placebo	Lasmitidan 100 mg/Lasmitidan 100 mg
	Started	501	249
Received at Least 1 Dose of Study Drug	429 <sup>[1]</sup>	225 <sup>[2]</sup>	423 <sup>[3]</sup>
Received Optional 2nd Dose	206 <sup>[4]</sup>	96 <sup>[5]</sup>	177 <sup>[6]</sup>
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	Lasmitidan 200 mg/Lasmitidan 200 mg	Lasmitidan 200 mg/Placebo
	Started	252	501
Received at Least 1 Dose of Study Drug	212 <sup>[7]</sup>	434 <sup>[8]</sup>	215 <sup>[9]</sup>
Received Optional 2nd Dose	83 <sup>[10]</sup>	144 <sup>[11]</sup>	74 <sup>[12]</sup>
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 <sup>[13]</sup>
Received Optional 2nd Dose	361 <sup>[14]</sup>
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

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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
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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
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End point description:

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

End point type	Primary
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End point timeframe:

2 hours post dose

<b>End point values</b>	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 <sup>[1]</sup>	532 <sup>[2]</sup>	528 <sup>[3]</sup>	539 <sup>[4]</sup>
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**

<b>Statistical analysis title</b>	Lasmiditan 200 mg
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Statistical analysis description:

Statistical analysis for Lasmiditan 200 mg compared with placebo

Comparison groups	Placebo v Lasmiditan 200 mg
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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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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 <sup>[5]</sup>	500 <sup>[6]</sup>	483 <sup>[7]</sup>	514 <sup>[8]</sup>
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**

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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	

<b>End point values</b>	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 <sup>[9]</sup>	571 <sup>[10]</sup>	565 <sup>[11]</sup>	576 <sup>[12]</sup>
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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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 <sup>[13]</sup>	167 <sup>[14]</sup>	205 <sup>[15]</sup>	115 <sup>[16]</sup>
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	

<b>End point values</b>	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 <sup>[17]</sup>	571 <sup>[18]</sup>	565 <sup>[19]</sup>	576 <sup>[20]</sup>
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**

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Other pre-specified: Percentage of Participants Use of rescue medication</b>	
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	

<b>End point values</b>	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 <sup>[21]</sup>	571 <sup>[22]</sup>	565 <sup>[23]</sup>	576 <sup>[24]</sup>
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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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 <sup>[25]</sup>	571 <sup>[26]</sup>	565 <sup>[27]</sup>	576 <sup>[28]</sup>
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	

<b>End point values</b>	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 <sup>[29]</sup>	571 <sup>[30]</sup>	565 <sup>[31]</sup>	576 <sup>[32]</sup>
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**

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Other pre-specified: Percentage of participants with phonophobia free</b>	
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	

<b>End point values</b>	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 <sup>[33]</sup>	571 <sup>[34]</sup>	565 <sup>[35]</sup>	576 <sup>[36]</sup>
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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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	

<b>End point values</b>	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 <sup>[37]</sup>	571 <sup>[38]</sup>	565 <sup>[39]</sup>	576 <sup>[40]</sup>
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**

<b>Statistical analysis title</b>	Lasmiditan 200 mg
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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	Lasmiditan 100 mg/Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	429 <sup>[41]</sup>	225 <sup>[42]</sup>	423 <sup>[43]</sup>	212 <sup>[44]</sup>
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	Lasmiditan 200 mg/Placebo	Placebo/Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	434 <sup>[45]</sup>	215 <sup>[46]</sup>	645 <sup>[47]</sup>	
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

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

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End point title	Number of Participants with Treatment Emergent Events
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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
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End point timeframe:

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

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<b>End point values</b>	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 <sup>[48]</sup>	635 <sup>[49]</sup>	649 <sup>[50]</sup>	645 <sup>[51]</sup>
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).

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**Statistical analyses**

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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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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### Reporting groups

Reporting group title	Lasmitidan 50 mg; Lasmitidan 50 mg
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Reporting group description:

Lasmitidan 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
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Reporting group description:

Lasmitidan 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
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Reporting group description:

Lasmitidan 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
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Reporting group description:

Lasmitidan 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
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Reporting group description:

Lasmitidan 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
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Reporting group description:

Lasmitidan 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
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Reporting group description:

Placebo tablets match each of the lasmitidan 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.

<b>Serious adverse events</b>	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
<b>Hepatobiliary disorders</b>			
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
<b>Psychiatric disorders</b>			
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

<b>Serious adverse events</b>	Lasmitidan 100 mg; Placebo	Lasmitidan 200 mg; Lasmitidan 200 mg	Lasmitidan 200 mg; Placebo
<b>Total subjects affected by serious adverse events</b>			
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
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
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
<b>Vascular disorders</b>			
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
<b>Surgical and medical procedures</b>			
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
<b>Nervous system disorders</b>			
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
<b>Gastrointestinal disorders</b>			
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
<b>Hepatobiliary disorders</b>			
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
<b>Psychiatric disorders</b>			
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

<b>Serious adverse events</b>	Placebo; Placebo		
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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 occurrences causally related to treatment / all deaths causally related to treatment / all	  1 / 646 (0.15%)  0 / 1  0 / 0		
Hepatobiliary disorders cholelithiasis alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  1 / 646 (0.15%)  0 / 1  0 / 0		
Psychiatric disorders somatisation disorder alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  0 / 646 (0.00%)  0 / 0  0 / 0		

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

<b>Non-serious adverse events</b>	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
<b>General disorders and administration site conditions</b>			
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

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

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

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

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

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

<b>Non-serious adverse events</b>	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 occurrences (all)	1 / 212 (0.47%) 1	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
pyrexia alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
sense of oppression alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
thirst alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	1 / 217 (0.46%) 1
Reproductive system and breast disorders menorrhagia alternative dictionary used: MedDRA 18.0 subjects affected / exposed <sup>[1]</sup> occurrences (all)	0 / 212 (0.00%) 0	2 / 364 (0.55%) 2	0 / 217 (0.00%) 0
ovarian cyst alternative dictionary used: MedDRA 18.0 subjects affected / exposed <sup>[2]</sup> occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
postmenopausal haemorrhage alternative dictionary used: MedDRA 18.0 subjects affected / exposed <sup>[3]</sup> occurrences (all)	0 / 212 (0.00%) 0	0 / 414 (0.00%) 0	0 / 202 (0.00%) 0
Respiratory, thoracic and mediastinal disorders chronic obstructive pulmonary disease alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 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 occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
throat tightness alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
Psychiatric disorders abnormal dreams alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
adjustment disorder alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
adjustment disorder with anxiety alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
anxiety alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	3 / 435 (0.69%) 3	1 / 217 (0.46%) 1
burnout syndrome alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
confusional state alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 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 occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
suicidal ideation alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
Investigations			
blood pressure decreased alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
blood pressure increased alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
heart rate increased alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
pulse pressure increased alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
Injury, poisoning and procedural complications			
arthropod sting alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
contusion alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
ligament sprain alternative dictionary used: MedDRA 18.0			

subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
skin abrasion alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
tendon injury alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
Cardiac disorders			
palpitations alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	1 / 435 (0.23%) 1	1 / 217 (0.46%) 2
tachycardia alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	1 / 217 (0.46%) 1
Nervous system disorders			
aphasia alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	1 / 217 (0.46%) 1
ataxia alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	2 / 435 (0.46%) 2	0 / 217 (0.00%) 0
aura alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 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 occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	1 / 217 (0.46%) 1
Ear and labyrinth disorders			
ear discomfort alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
motion sickness alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
tinnitus alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
vertigo alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 3	3 / 435 (0.69%) 3	2 / 217 (0.92%) 2
Eye disorders			
blepharospasm alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
chromatopsia alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
keratitis alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 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 occurrences (all)	0 / 212 (0.00%) 0	3 / 435 (0.69%) 3	0 / 217 (0.00%) 0
retching alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
toothache alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
vomiting alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 2	3 / 435 (0.69%) 3	3 / 217 (1.38%) 3
<b>Skin and subcutaneous tissue disorders</b>			
hyperhidrosis alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
pruritus alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
pruritus generalised alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
<b>Renal and urinary disorders</b>			
urinary incontinence alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
<b>Endocrine disorders</b>			

hyperthyroidism alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
Musculoskeletal and connective tissue disorders			
arthralgia alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
back pain alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	2 / 435 (0.46%) 2	1 / 217 (0.46%) 1
muscle spasms alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
muscle twitching alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	2 / 435 (0.46%) 2	2 / 217 (0.92%) 2
muscular weakness alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	4 / 212 (1.89%) 4	7 / 435 (1.61%) 7	2 / 217 (0.92%) 2
musculoskeletal chest pain alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
musculoskeletal pain alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 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
<b>Infections and infestations</b>			
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 occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
nasopharyngitis alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
rhinitis alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
sinusitis alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0
upper respiratory tract infection alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 2	3 / 435 (0.69%) 3	2 / 217 (0.92%) 2
urinary tract infection alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
viral upper respiratory tract infection alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	0 / 435 (0.00%) 0	0 / 217 (0.00%) 0
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 18.0			
subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 435 (0.23%) 1	0 / 217 (0.00%) 0

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

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

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			

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

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		

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

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			

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

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

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

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

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		

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

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

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

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported