



## Clinical trial results:

### A Double-blind, Placebo-controlled, Parallel-group Study With an Open-label Extension Phase to Evaluate the Efficacy and Safety of Perampanel (E2007) Administered as an Adjunctive Therapy in Subjects With Refractory Partial-onset Seizures

#### Summary

EudraCT number	2020-002109-24
Trial protocol	Outside EU/EEA
Global end of trial date	28 May 2020

#### Results information

Result version number	v1 (current)
This version publication date	13 December 2020
First version publication date	13 December 2020

#### Trial information

##### Trial identification

Sponsor protocol code	E2007-J000-335
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01618695
WHO universal trial number (UTN)	-
Other trial identifiers	China: CTR20131839, Japan: JapicCTI-121906

Notes:

#### Sponsors

Sponsor organisation name	Eisai Co., Ltd.
Sponsor organisation address	4-6-10 Koishikawa, Bunkyo-Ku, Tokyo, Japan, 112-8088
Public contact	Inquiry Service., Eisai Co., Ltd., eisai-chiken_hotline@hhc.eisai.co.jp
Scientific contact	Inquiry Service., Eisai Co., Ltd., eisai-chiken_hotline@hhc.eisai.co.jp

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?	Yes

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 May 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	28 May 2020
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary purpose of this trial was to confirm the efficacy of perampanel (4 milligram [mg], 8 mg and 12 mg) compared to placebo given as an adjunctive therapy in subjects with refractory partial-onset seizures.

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures of the sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following: - Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008). - International Council on Harmonisation (ICH) E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. - Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board regulations and applicable sections of US 21 CFR Part 312. - European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions were reported, as required, to the Competent Authorities of all involved EU member states. - Article 14, Paragraph 3, and Article 80-2 of the Pharmaceutical Affairs Law (Law No. 145, 1960) for studies conducted in Japan, in addition to Japan's GCP Subject Information and Informed Consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 May 2012
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	Korea, Republic of: 171
Country: Number of subjects enrolled	Thailand: 36
Country: Number of subjects enrolled	Malaysia: 14
Country: Number of subjects enrolled	Japan: 245
Country: Number of subjects enrolled	China: 185
Country: Number of subjects enrolled	Australia: 44
Country: Number of subjects enrolled	Taiwan: 12
Worldwide total number of subjects	707
EEA total number of subjects	0

Notes:

<b>Subjects enrolled per age group</b>	
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)	74
Adults (18-64 years)	623
From 65 to 84 years	10
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Subjects took part in the study at 119 investigative sites in Australia, China, Korea, Japan, Malaysia, Taiwan, and Thailand from 15th May 2012 to 28th May 2020.

### Pre-assignment

Screening details:

A total of 940 subjects were enrolled and screened, of which 230 subjects were screen failures, 710 subjects were randomized and 707 subjects were treated in this study. This study included Core Phase and an Extension Phase.

### 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, Carer, Assessor

### Arms

Are arms mutually exclusive?	No
<b>Arm title</b>	Core Phase: Placebo

Arm description:

Subjects received perampanel-matched placebo tablets (6 tablets), orally, once daily before bedtime from Week 0 up to Week 18 (up to 19 weeks).

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

Dosage and administration details:

Subjects received perampanel-matched placebo tablets (6 tablets), orally, once daily before bedtime.

<b>Arm title</b>	Core Phase: Perampanel 4 mg
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Arm description:

Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 4 mg orally once daily from Week 1 up to Week 5 (titration period), followed by perampanel 4 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel 2 mg (administered as a single tablet) orally, once daily before bedtime and then titrated up to maximum dose of 4 mg (administered as two 2 mg tablets) orally, once daily (titration period), followed by perampanel 4 mg orally, once daily (maintenance period). Each perampanel tablet contained 2 mg, subjects also received either 5 or 4 placebo tablets to ensure all subjects received 6 tablets regardless of the perampanel dose.

<b>Arm title</b>	Core Phase: Perampanel 8 mg
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**Arm description:**

Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 8 mg (weekly increment of 2 mg from Week 1 up to Week 3) orally once daily for up to Week 5 (titration period), followed by perampanel 8 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

**Dosage and administration details:**

Subjects received perampanel 2 mg (administered as a single tablet) orally, once daily before bedtime and then titrated up to maximum dose of 8 mg (administered as four 2 mg tablets with weekly increments of 2 mg) orally, once daily (titration period), followed by perampanel 8 mg orally, once daily (maintenance period). Each perampanel tablet contained 2 mg, subjects also received 5, 4, 3 or 2 placebo tablets to ensure all subjects received 6 tablets regardless of the perampanel dose.

<b>Arm title</b>	Core Phase: Perampanel 12 mg
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**Arm description:**

Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 12 mg (weekly increment of 2 mg from Week 1 up to Week 5) orally once daily for up to Week 5 (titration period), followed by perampanel 12 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

**Dosage and administration details:**

Subjects received perampanel 2 mg (administered as a single tablet) orally, once daily before bedtime and then titrated up to maximum dose of 12 mg (administered as six 2 mg tablets with weekly increments of 2 mg from Week 1 up to Week 5) orally, once daily (titration period), followed by perampanel 12 mg orally, once daily (maintenance period). Each perampanel tablet contained 2 mg, subjects also received 5, 4, 3, 2, 1 or 0 placebo tablets to ensure all subjects received 6 tablets regardless of the perampanel dose.

<b>Arm title</b>	Extension Phase: Perampanel 12 mg
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**Arm description:**

Subjects received the same dose of perampanel in Extension Phase as they received in Core Phase, orally, once daily before bedtime from Week 19 to Week 22 (preconversion period). This dose was then titrated as 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). Subjects who received perampanel matched-placebo in Core Phase were given perampanel 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). A maintenance period was followed by conversion period in which subjects received perampanel 12 mg, orally once daily before bedtime up to Week 75 or longer depending on the requirements of each country.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

**Dosage and administration details:**

Subjects received the same dose of perampanel in Extension Phase as they received in Core Phase, orally once daily before bedtime from Week 19 to Week 22 (preconversion period) and then dose was up titrated as 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). Subjects who received perampanel matched-placebo in Core Phase were given perampanel 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). A maintenance period was followed by conversion period in which subjects received

perampanel 12 mg, orally once daily before bedtime up to Week 75 or longer depending on the requirements of each country. Each perampanel tablet contained 2 mg, subjects also received 5, 4, 3, 2, 1 or 0 placebo tablets to ensure all subjects received 6 tablets regardless of the perampanel dose.

<b>Number of subjects in period 1</b>	Core Phase: Placebo	Core Phase: Perampanel 4 mg	Core Phase: Perampanel 8 mg
Started	176	176	175
Completed	152	156	147
Not completed	24	20	28
Consent withdrawn by subject	16	11	9
Pregnancy	2	-	-
Other than specified	1	2	2
Adverse Events	4	5	15
Lost to follow-up	-	-	1
Lack of efficacy	1	2	1

<b>Number of subjects in period 1</b>	Core Phase: Perampanel 12 mg	Extension Phase: Perampanel 12 mg
Started	180	596
Completed	144	196
Not completed	36	400
Consent withdrawn by subject	13	166
Pregnancy	-	4
Other than specified	2	62
Adverse Events	20	63
Lost to follow-up	-	5
Lack of efficacy	1	100

## Baseline characteristics

### Reporting groups

Reporting group title	Overall Study
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Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	707	707	
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	33.4		
standard deviation	± 13.21	-	
Gender categorical			
Units: Subjects			
Female	361	361	
Male	346	346	
Ethnicity			
Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	705	705	
Unknown or Not Reported	0	0	
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	667	667	
Native Hawaiian or Other Pacific Islander	1	1	
Black or African American	0	0	
White	35	35	
More than one race	0	0	
Unknown or Not Reported	4	4	

## End points

### End points reporting groups

Reporting group title	Core Phase: Placebo
Reporting group description: Subjects received perampanel-matched placebo tablets (6 tablets), orally, once daily before bedtime from Week 0 up to Week 18 (up to 19 weeks).	
Reporting group title	Core Phase: Perampanel 4 mg
Reporting group description: Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 4 mg orally once daily from Week 1 up to Week 5 (titration period), followed by perampanel 4 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.	
Reporting group title	Core Phase: Perampanel 8 mg
Reporting group description: Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 8 mg (weekly increment of 2 mg from Week 1 up to Week 3) orally once daily for up to Week 5 (titration period), followed by perampanel 8 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.	
Reporting group title	Core Phase: Perampanel 12 mg
Reporting group description: Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 12 mg (weekly increment of 2 mg from Week 1 up to Week 5) orally once daily for up to Week 5 (titration period), followed by perampanel 12 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.	
Reporting group title	Extension Phase: Perampanel 12 mg
Reporting group description: Subjects received the same dose of perampanel in Extension Phase as they received in Core Phase, orally, once daily before bedtime from Week 19 to Week 22 (preconversion period). This dose was then titrated as 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). Subjects who received perampanel matched-placebo in Core Phase were given perampanel 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). A maintenance period was followed by conversion period in which subjects received perampanel 12 mg, orally once daily before bedtime up to Week 75 or longer depending on the requirements of each country.	

### Primary: Core Phase: Percent Change in Seizure Frequency (For All Partial Seizures) Per 28 Days in the Randomization Phase Relative to Pre-randomization Phase (Baseline)

End point title	Core Phase: Percent Change in Seizure Frequency (For All Partial Seizures) Per 28 Days in the Randomization Phase Relative to Pre-randomization Phase (Baseline) <sup>[1]</sup>
End point description: Seizure frequency was based on number of seizures per 28 days, calculated as the number of seizures over the entire time interval divided by the number of days in the interval and multiplied by 28. All partial seizure included simple partial seizures without motor signs, simple partial with motor signs, complex partial, and complex partial with secondary generalized seizures. A simple partial seizure takes place on one side of the brain. Usually, people experiencing a simple partial seizure do not lose consciousness or awareness. A complex partial seizure is a type of seizure that arises in one lobe of the brain, rather than the whole brain. The seizure affects people's awareness and may cause them to lose consciousness. Intent-to-treat (ITT) Analysis Set included all subjects who signed informed consent, were randomized, received at least one dose of study medication, and have at least one postdose seizure frequency data.	
End point type	Primary
End point timeframe: Baseline, Week 19	



Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: This endpoint was only planned to be analyzed for the reporting groups of Core Phase.

End point values	Core Phase: Placebo	Core Phase: Perampanel 4 mg	Core Phase: Perampanel 8 mg	Core Phase: Perampanel 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	175	174	175	180
Units: percent change				
median (full range (min-max))	-10.76 (-90.4 to 400.0)	-17.32 (-97.1 to 473.4)	-28.95 (-100.0 to 809.4)	-38.03 (-100.0 to 456.8)

## Statistical analyses

Statistical analysis title	Placebo, Perampanel 4 mg
Statistical analysis description: Median Difference to placebo and the 95 percent (%) confidence interval are based on the Hodges-Lehmann method.	
Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 4 mg
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.233
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-5.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.112
upper limit	4.519

Statistical analysis title	Placebo, Perampanel 8 mg
Statistical analysis description: Median Difference to placebo and the 95% confidence interval are based on the Hodges-Lehmann method.	
Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 8 mg
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-16.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.683
upper limit	-7.251

<b>Statistical analysis title</b>	Placebo, Perampanel 12 mg
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Statistical analysis description:

Median Difference to placebo and the 95% confidence interval are based on the Hodges-Lehmann method.

Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 12 mg
Number of subjects included in analysis	355
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-24.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.878
upper limit	-16.235

### **Secondary: Core Phase: Responder Rate During the Maintenance Period of the Randomization Phase Relative to the Prerandomization Phase (Baseline)- Last Observation Carried Forward (LOCF)**

End point title	Core Phase: Responder Rate During the Maintenance Period of the Randomization Phase Relative to the Prerandomization Phase (Baseline)- Last Observation Carried Forward (LOCF) <sup>[2]</sup>
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End point description:

Responder rate was percentage of subjects with greater than or equal to ( $\geq$ ) 50% reduction in seizure frequency during maintenance period of the randomization phase relative to prerandomization phase (baseline). If the reduction in seizure frequency is less than ( $<$ ) 50%, then the subjects are considered as non-responders. ITT Analysis Set included all subjects who signed informed consent, were randomized, received at least one dose of study medication, and have at least one postdose seizure frequency data.

End point type	Secondary
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End point timeframe:

Baseline, Week 19

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was only planned to be analyzed for the reporting groups of Core Phase.

End point values	Core Phase: Placebo	Core Phase: Perampanel 4 mg	Core Phase: Perampanel 8 mg	Core Phase: Perampanel 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	175	174	175	180
Units: percentage of subjects				
number (not applicable)	19.4	23.0	36.0	43.3

## Statistical analyses

<b>Statistical analysis title</b>	Placebo, Perampanel 4 mg
Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 4 mg
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3954
Method	Cochran-Mantel-Haenszel

<b>Statistical analysis title</b>	Placebo, Perampanel 8 mg
Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 8 mg
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005
Method	Cochran-Mantel-Haenszel

<b>Statistical analysis title</b>	Placebo, Perampanel 12 mg
Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 12 mg
Number of subjects included in analysis	355
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel

## Secondary: Core Phase: Percent Change in Seizure Frequency Per 28 Days For Complex Partial Seizures Plus Secondary Generalized Seizures in the Randomization Phase Relative to the Prerandomization Phase (Baseline)

End point title	Core Phase: Percent Change in Seizure Frequency Per 28 Days For Complex Partial Seizures Plus Secondary Generalized Seizures in the Randomization Phase Relative to the Prerandomization Phase (Baseline) <sup>[3]</sup>
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End point description:

Seizure frequency was based on number of seizures per 28 days, calculated as the number of seizures

over the entire time interval divided by the number of days in the interval and multiplied by 28. A complex partial seizure is a type of seizure that arises in one lobe of the brain, rather than the whole brain and it affects awareness and may cause in loss of consciousness. Secondary generalized seizures begin in one part of the brain, but then spread to both sides of the brain. ITT Analysis Set included all subjects who signed informed consent, were randomized, received at least one dose of study medication, and have at least one postdose seizure frequency data. Here "subjects analyzed" signifies subjects who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline, Week 19

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analyzed for the reporting groups of Core Phase.

End point values	Core Phase: Placebo	Core Phase: Perampanel 4 mg	Core Phase: Perampanel 8 mg	Core Phase: Perampanel 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	158	151	157	167
Units: percent change				
median (full range (min-max))	-11.70 (-88.6 to 400.0)	-19.08 (-100.0 to 410.0)	-33.68 (-100.0 to 1103.4)	-41.80 (-100.0 to 456.8)

## Statistical analyses

<b>Statistical analysis title</b>	Placebo, Perampanel 4 mg
Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 4 mg
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	superiority <sup>[4]</sup>
P-value	= 0.0552
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-8.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.067
upper limit	1.671

Notes:

[4] - Median Difference to placebo and the 95% confidence interval are based on the Hodges-Lehmann method.

<b>Statistical analysis title</b>	Placebo, Perampanel 8 mg
Statistical analysis description:	
Median Difference to placebo and the 95% confidence interval are based on the Hodges-Lehmann method.	
Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 8 mg

Number of subjects included in analysis	315
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-21.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.941
upper limit	-11.368

<b>Statistical analysis title</b>	Placebo, Perampanel 12 mg
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Statistical analysis description:

Median Difference to placebo and the 95% confidence interval are based on the Hodges-Lehmann method.

Comparison groups	Core Phase: Placebo v Core Phase: Perampanel 12 mg
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-28.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.698
upper limit	-19.794

### **Secondary: Core Phase: Number of Subjects With Clinical Global Impression of Change (CGIC) Scores**

End point title	Core Phase: Number of Subjects With Clinical Global Impression of Change (CGIC) Scores <sup>[5]</sup>
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End point description:

The investigator evaluated each subject for CGIC questionnaire to assess change in subject's disease clinical status from baseline. Assessment evaluated frequency of seizures, severity of seizures, occurrence of adverse events, and overall functional status of the subject using the 7-point scale. The evaluation used a 7-point scale with the scores 1: Very much improved, 2: Much improved, 3: Minimally improved, 4: No change, 5: Minimally worse, 6: Much worse, 7: Very much worse. Lower score indicated improvement. Higher score indicated worsening. ITT Analysis Set included all subjects who signed informed consent, were randomized, received at least one dose of study medication, and have at least one postdose seizure frequency data.

End point type	Secondary
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End point timeframe:

Baseline, Week 19

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analyzed for the reporting groups of Core Phase.

Only descriptive data was planned to be analyzed for this endpoint.

<b>End point values</b>	Core Phase: Placebo	Core Phase: Perampanel 4 mg	Core Phase: Perampanel 8 mg	Core Phase: Perampanel 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	175	174	175	180
Units: subjects				
Very much improved	3	5	11	9
Much improved	31	39	41	54
Minimally improved	54	45	53	40
No change	67	56	37	37
Minimally worse	3	10	5	4
Much worse	1	0	0	1
Very much worse	0	0	0	1

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From the date of first dose up to 30 days after the last dose of study drug (up to Week 79)

Adverse event reporting additional description:

Safety Analysis Set included all subjects who signed informed consent, were randomized, received at least one dose of study medication, and have at least one post-dose safety assessment.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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### Reporting groups

Reporting group title	Core Phase: Placebo
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Reporting group description:

Subjects received perampanel-matched placebo tablets (6 tablets), orally, once daily before bedtime from Week 0 up to Week 18 (up to 19 weeks).

Reporting group title	Core Phase: Perampanel 4 mg
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Reporting group description:

Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 4 mg orally once daily from Week 1 up to Week 5 (titration period), followed by perampanel 4 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.

Reporting group title	Core Phase: Perampanel 8 mg
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Reporting group description:

Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 8 mg (weekly increment of 2 mg from Week 1 up to Week 3) orally once daily for up to Week 5 (titration period), followed by perampanel 8 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.

Reporting group title	Core Phase: Perampanel 12 mg
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Reporting group description:

Subjects received perampanel 2 mg tablet, orally once daily before bedtime in Week 0 and then titrated up to maximum dose of 12 mg (weekly increment of 2 mg from Week 1 up to Week 5) orally once daily for up to Week 5 (titration period), followed by perampanel 12 mg, orally once daily from Week 6 up to Week 18 (maintenance period). Total duration of titration and maintenance period was 19 weeks.

Reporting group title	Extension Phase: Perampanel 12 mg
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Reporting group description:

Subjects received the same dose of perampanel in Extension Phase as they received in Core Phase, orally, once daily before bedtime from Week 19 to Week 22 (preconversion period). This dose was then titrated as 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). Subjects who received perampanel matched-placebo in Core Phase were given perampanel 2 mg weekly increments up to a maximum dose of 12 mg, orally once daily up to Week 28 (conversion period). A maintenance period was followed by conversion period in which subjects received perampanel 12 mg, orally once daily before bedtime up to Week 75 or longer depending on the requirements of each country. Safety analysis set for Extension Phase included 679 subjects. This included 596 who were treated with at least one dose of perampanel in Extension Phase and 83 subjects who were treated with perampanel in Core Phase but were withdrawn during Core Phase and did not enter Extension Phase.

Serious adverse events	Core Phase: Placebo	Core Phase: Perampanel 4 mg	Core Phase: Perampanel 8 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 176 (5.68%)	6 / 176 (3.41%)	7 / 175 (4.00%)

number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Benign hydatidiform mole			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Brain neoplasm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Breast cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Colon cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Fibroadenoma of breast			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Vascular disorders			
Aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Thrombophlebitis superficial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion induced			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sudden cardiac death			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sudden unexplained death in			

epilepsy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Adenomyosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Asphyxia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Pneumonia aspiration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Pneumothorax			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Aggression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Suicide attempt			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute psychosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Conversion disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Self-injurious ideation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Anxiety disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Bipolar disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Delusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Emotional disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Hallucination, auditory			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Irritability			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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

Mental disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Postictal psychosis alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Psychogenic seizure alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Psychotic disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Psychotic disorder due to a general medical condition alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Suicidal behaviour alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications Brain contusion alternative dictionary used:			

MedDRA 21.1				
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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	
Burns second degree				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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	
Facial bones fracture				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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	
Road traffic accident				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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	
Contusion				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Ankle fracture				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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	
Clavicle fracture				
alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Fibula fracture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Foot fracture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Head injury alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Intentional overdose alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Limb injury alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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

Lumbar vertebral fracture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Meniscus injury alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Patella fracture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Pelvic fracture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Skin laceration alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Spinal compression fracture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Thermal burn alternative dictionary used: MedDRA 21.1			



subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Sinus node dysfunction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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			
Epilepsy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (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
Complex partial seizures			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand mal convulsion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (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
Altered state of consciousness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Ataxia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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

Cerebral infarction alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Dizziness alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Dysarthria alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Focal dyscognitive seizures alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Generalised tonic-clonic seizure alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Idiopathic partial epilepsy alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Lacunar infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Limbic encephalitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Normal pressure hydrocephalus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Seizure cluster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Somnolence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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

Subarachnoid haemorrhage alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 175 (0.00%) 0 / 0 0 / 0
Blood and lymphatic system disorders Immune thrombocytopenic purpura alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 175 (0.00%) 0 / 0 0 / 0
Eye disorders Cataract alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 175 (0.00%) 0 / 0 0 / 0
Lens dislocation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 175 (0.00%) 0 / 0 0 / 0
Gastrointestinal disorders Haemorrhoids alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 175 (0.00%) 0 / 0 0 / 0
Gastrointestinal haemorrhage alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 176 (0.57%) 0 / 1 0 / 1	0 / 176 (0.00%) 0 / 0 0 / 0	0 / 175 (0.00%) 0 / 0 0 / 0
Diarrhoea			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Enterocolitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Gingival hypertrophy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Haematemesis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Skin and subcutaneous tissue disorders			
Excessive granulation tissue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (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
Rash			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Renal and urinary disorders			
Ureterolithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Urinary retention			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Rotator cuff syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Gastroenteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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



Herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Periodontitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Post procedural infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Sepsis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Urinary tract infection alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Metabolism and nutrition disorders			
Diabetes mellitus alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Hyperkalaemia alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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
Hyponatraemia alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (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>	Core Phase: Perampanel 12 mg	Extension Phase: Perampanel 12 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 180 (6.67%)	113 / 679 (16.64%)	
number of deaths (all causes)	0	7	
number of deaths resulting from adverse events	0	7	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Acute promyelocytic leukaemia alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign hydatidiform mole alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibroadenoma of breast alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders Aneurysm alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abortion induced			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sudden cardiac death			
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden unexplained death in epilepsy			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Reproductive system and breast disorders			
Adenomyosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia aspiration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Aggression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	3 / 679 (0.44%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)	
occurrences causally related to treatment / all	0 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute psychosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Self-injurious ideation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emotional disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, auditory			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritability			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Mental disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postictal psychosis alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic seizure alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder due to a general medical condition alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal behaviour alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications Brain contusion alternative dictionary used:			



MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intentional overdose			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Lumbar vertebral fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Meniscus injury alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Patella fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Pelvic fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Skin laceration alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)		
occurrences causally related to treatment / all	0 / 0	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
Spinal compression fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Thermal burn alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Epilepsy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	5 / 679 (0.74%)	
occurrences causally related to treatment / all	1 / 1	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	6 / 679 (0.88%)	
occurrences causally related to treatment / all	1 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complex partial seizures			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Grand mal convulsion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cerebral infarction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 0		
Cerebrovascular accident alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 0		
Dizziness alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	2 / 679 (0.29%) 2 / 2 0 / 0		
Dysarthria alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 1 / 1 0 / 0		
Focal dyscognitive seizures alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 0		
Generalised tonic-clonic seizure alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 0		
Idiopathic partial epilepsy alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limbic encephalitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure cluster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Subarachnoid haemorrhage alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 0	
Blood and lymphatic system disorders Immune thrombocytopenic purpura alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 1	
Eye disorders Cataract alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	4 / 679 (0.59%) 0 / 4 0 / 0	
Lens dislocation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 0	
Gastrointestinal disorders Haemorrhoids alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 180 (0.56%) 0 / 1 0 / 0	1 / 679 (0.15%) 0 / 1 0 / 0	
Gastrointestinal haemorrhage alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 180 (0.00%) 0 / 0 0 / 0	0 / 679 (0.00%) 0 / 0 0 / 0	
Diarrhoea			



alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival hypertrophy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Excessive granulation tissue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Ureterolithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Anal abscess			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

<b>Non-serious adverse events</b>	Core Phase: Placebo	Core Phase: Perampanel 4 mg	Core Phase: Perampanel 8 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	114 / 176 (64.77%)	119 / 176 (67.61%)	127 / 175 (72.57%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Acrochordon			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Benign breast neoplasm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Benign hepatobiliary neoplasm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Leiomyoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Hypotension			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Angiodysplasia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Hyperaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Wisdom teeth removal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Irritability			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	8 / 176 (4.55%)	10 / 175 (5.71%)
occurrences (all)	1	9	10
Fatigue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 176 (2.84%)	4 / 176 (2.27%)	6 / 175 (3.43%)
occurrences (all)	5	4	6
Gait disturbance			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 176 (1.70%)	2 / 176 (1.14%)	4 / 175 (2.29%)
occurrences (all)	3	2	4
Pyrexia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 176 (1.70%)	2 / 176 (1.14%)	4 / 175 (2.29%)
occurrences (all)	6	2	4
Asthenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	1	0	2
Malaise			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	2 / 175 (1.14%)
occurrences (all)	0	1	2
Feeling abnormal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	0	1	1
Face oedema			
alternative dictionary used: MedDRA 21.1			



subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Foreign body reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Oedema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Chest pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Chills			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Decreased activity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Feeling hot alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Generalised oedema alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Oedema peripheral alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Peripheral swelling alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Thirst alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Immune system disorders Allergy to arthropod sting alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Seasonal allergy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Social circumstances Hearing aid user alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Reproductive system and breast disorders			

Prostatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Cervical cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Cervical polyp			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hypomenorrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Menorrhagia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Menstrual disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Menstruation irregular			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Pelvic fluid collection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Scrotal swelling			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	4	0	0
Amenorrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Benign prostatic hyperplasia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Breast tenderness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Genital haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Menopausal symptoms			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Menstruation delayed			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Oligomenorrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Ovarian cyst alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Pelvic pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Scrotal inflammation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Sexual dysfunction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Vaginal discharge alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Laryngeal discomfort alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	2 / 176 (1.14%) 2	0 / 175 (0.00%) 0
Epistaxis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	1 / 176 (0.57%) 1	1 / 175 (0.57%) 1
Rhinitis allergic alternative dictionary used:			

MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Upper respiratory tract inflammation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	3	0	1
Dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Hiccups			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Productive cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 176 (1.70%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	4	1	0
Sneezing			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Wheezing			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Asthma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hyperventilation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Pneumonia aspiration alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Respiratory tract congestion alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Sputum increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Tonsillar inflammation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Vasomotor rhinitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Psychiatric disorders Aggression alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	4 / 176 (2.27%) 4	5 / 175 (2.86%) 5
Suicidal ideation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	3 / 176 (1.70%) 3	7 / 175 (4.00%) 7
Anxiety alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	6 / 175 (3.43%) 6
Insomnia alternative dictionary used: MedDRA 21.1			



subjects affected / exposed	7 / 176 (3.98%)	3 / 176 (1.70%)	2 / 175 (1.14%)
occurrences (all)	7	4	2
Mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	3 / 176 (1.70%)	2 / 175 (1.14%)
occurrences (all)	1	3	2
Anger			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	1	0	1
Depression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2
Affect lability			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Depressed mood			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	2 / 175 (1.14%)
occurrences (all)	1	1	2
Abnormal behaviour			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Hallucination, auditory			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	0	2	0
Mood altered			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1

Sleep disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	1	2	0
Affective disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Agitation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Anxiety disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Confusional arousal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Emotional disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Expressive language disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Fear			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Impatience			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Nervousness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Obsessive-compulsive disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Personality change			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Personality disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Regressive behaviour			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Restlessness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Self-injurious ideation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Sleep talking			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1

Soliloquy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Stubbornness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Suicide attempt			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Thinking abnormal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Tic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Abnormal dreams			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Acute stress disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Intentional self-injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	2	0	0
Panic attack			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Bipolar disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Bruxism			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Confusional state			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Conversion disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Delusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Depressive symptom			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dissociative disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Enuresis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Hallucination			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Impulsive behaviour			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Major depression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Mania			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Mental disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Mixed anxiety and depressive disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Neurosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Nightmare			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Panic disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Paranoia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Persecutory delusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Psychogenic seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Somatic symptom disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Stress			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Suicidal behaviour			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Product issues Device breakage alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Product blister packaging issue alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0  0 / 176 (0.00%) 0	0 / 176 (0.00%) 0  0 / 176 (0.00%) 0	0 / 175 (0.00%) 0  0 / 175 (0.00%) 0
Hepatobiliary disorders Hepatic function abnormal alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Cholecystitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Cholelithiasis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Hepatic mass alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Hepatic steatosis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0  1 / 176 (0.57%) 1  0 / 176 (0.00%) 0  0 / 176 (0.00%) 0  0 / 176 (0.00%) 0	0 / 176 (0.00%) 0  0 / 176 (0.00%) 0  0 / 176 (0.00%) 0  0 / 176 (0.00%) 0  0 / 176 (0.00%) 0	1 / 175 (0.57%) 1  0 / 175 (0.00%) 0  0 / 175 (0.00%) 0  0 / 175 (0.00%) 0
Investigations Weight increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Blood creatine phosphokinase	1 / 176 (0.57%) 1	7 / 176 (3.98%) 8	6 / 175 (3.43%) 6



increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	2 / 175 (1.14%)
occurrences (all)	0	2	2
Electrocardiogram QT prolonged			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	1	2	0
Blood phosphorus decreased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Protein urine present			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	2	0	2
Weight decreased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	1	0	2
Blood cholesterol increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Blood uric acid increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	0	2	0
Gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone abnormal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Blood sodium decreased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides abnormal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	1	0	1
Monocyte count increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Neutrophil count decreased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Platelet count decreased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	1 / 175 (0.57%) 1
Red blood cells urine alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Urine ketone body present alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Vitamin D decreased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	1 / 175 (0.57%) 1
Blood glucose increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Blood triglycerides increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Blood urine present alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 2	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Anticonvulsant drug level increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Blood bicarbonate decreased alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood magnesium abnormal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase abnormal			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Liver function test increased alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Thyroxine free decreased alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Urine uric acid increased alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

<p>White blood cell count increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 175 (0.00%)</p> <p>0</p>
<p>pH urine increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 175 (0.00%)</p> <p>0</p>
<p>Injury, poisoning and procedural complications</p> <p>Contusion</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Joint sprain</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Excoriation</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Foot fracture</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Skin laceration</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Thermal burn</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Wound</p> <p>alternative dictionary used:</p>	<p>4 / 176 (2.27%)</p> <p>5</p> <p>0 / 176 (0.00%)</p> <p>0</p> <p>3 / 176 (1.70%)</p> <p>3</p> <p>1 / 176 (0.57%)</p> <p>1</p> <p>3 / 176 (1.70%)</p> <p>3</p> <p>0 / 176 (0.00%)</p> <p>0</p>	<p>5 / 176 (2.84%)</p> <p>19</p> <p>3 / 176 (1.70%)</p> <p>3</p> <p>1 / 176 (0.57%)</p> <p>1</p> <p>0 / 176 (0.00%)</p> <p>0</p>	<p>6 / 175 (3.43%)</p> <p>6</p> <p>2 / 175 (1.14%)</p> <p>2</p> <p>1 / 175 (0.57%)</p> <p>1</p> <p>1 / 175 (0.57%)</p> <p>1</p> <p>1 / 175 (0.57%)</p> <p>1</p>

MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Animal bite			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Fall			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	2	0	2
Head injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	0	2	0
Limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	0	1	1
Lip injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Rib fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	1	1	1
Ankle fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Arthropod sting			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	2
Burns second degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Heat stroke			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Ligament rupture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Multiple injuries			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Periorbital haematoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Radius fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Road traffic accident			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0



Stab wound			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Sunburn			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Tibia fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Tooth fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Tooth injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Wrist fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Scratch			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Bone fissure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Burns first degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Chemical poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Chest injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Chillblains			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Closed globe injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Concussion			
alternative dictionary used: MedDRA 21.11			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Compression fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Conjunctival abrasion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ear canal abrasion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eye injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eyelid contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eyelid injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Face injury			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Heat illness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Joint injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ligament injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Neck injury alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Patella fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Post-traumatic neck syndrome alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Procedural pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Scar alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Skin abrasion alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Skin injury alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Skin wound alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Soft tissue injury alternative dictionary used: MedDRA 21.1			

subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Subcutaneous haematoma alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Subdural haematoma alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Tooth dislocation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Toxicity to various agents alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Upper limb fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Congenital, familial and genetic disorders Hypophosphatasia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Cardiac disorders Angina pectoris alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Atrial fibrillation alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Palpitations			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	10 / 176 (5.68%)	40 / 176 (22.73%)	50 / 175 (28.57%)
occurrences (all)	11	48	60
Somnolence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	23 / 176 (13.07%)	28 / 176 (15.91%)	31 / 175 (17.71%)
occurrences (all)	24	28	36
Headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	13 / 176 (7.39%)	12 / 176 (6.82%)	13 / 175 (7.43%)
occurrences (all)	18	22	14
Ataxia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	1 / 175 (0.57%)
occurrences (all)	0	2	1
Balance disorder			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	4 / 176 (2.27%)	1 / 175 (0.57%)
occurrences (all)	0	4	1
Dysarthria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	3 / 175 (1.71%)
occurrences (all)	1	0	3
Hypoaesthesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	3 / 176 (1.70%)	1 / 175 (0.57%)
occurrences (all)	1	4	1
Tremor			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	1	2	0
Convulsion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	1	2	0
Memory impairment			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	0	1	1
Nystagmus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	1 / 175 (0.57%)
occurrences (all)	0	2	1
Amnesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	1 / 175 (0.57%)
occurrences (all)	0	2	1
Complex partial seizures			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2



Dementia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Lethargy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2
Paraesthesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	1	0	2
Aphasia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Clumsiness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Cranial nerve disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Dizziness postural			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Dyskinesia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Dystonia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Hypersomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	2
Migraine			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Nerve root compression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Psychomotor hyperactivity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Anaesthesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Dyslalia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Grand mal convulsion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Partial seizures with secondary generalisation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 176 (1.70%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	3	0	0
Syncope			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	2	0	0
Tongue biting			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Burning sensation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Cerebral disorder			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Change in seizure presentation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Drooling			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dysstasia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Epilepsy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Focal dyscognitive seizures			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hemiplegia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hyposmia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Language disorder			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Postictal headache			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Postural tremor			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Radial nerve palsy			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Seizure			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Seizure cluster			
alternative dictionary used:			
MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Sleep deficit			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Slow response to stimuli			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Status epilepticus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Tonic convulsion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Lymphadenitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2
Eosinophilia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Leukopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	3 / 176 (1.70%)	5 / 175 (2.86%)
occurrences (all)	1	3	6
Cerumen impaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Deafness neurosensory			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ear pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
alternative dictionary used: MedDRA 21.1			



subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Vertigo positional alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Eye disorders			
Vision blurred alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	2 / 176 (1.14%) 2	2 / 175 (1.14%) 2
Asthenopia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	1 / 175 (0.57%) 1
Conjunctivitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Diplopia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	2 / 175 (1.14%) 2
Eyelid oedema alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Visual impairment alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Cataract alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Chalazion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dry eye			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Dysmetropsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Glaucoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Keratoconjunctivitis sicca			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Normal tension glaucoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Retinal disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Vitreous floaters			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eye pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Blepharitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Borderline glaucoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Corneal erosion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Diabetic retinopathy			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Excessive eye blinking			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eyelid myoclonus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Keratitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Psychogenic visual disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Punctate keratitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Swelling of eyelid alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Visual acuity reduced alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Xerophthalmia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Gastrointestinal disorders Nausea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	6 / 176 (3.41%) 6	4 / 176 (2.27%) 4	4 / 175 (2.29%) 4
Diarrhoea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	6 / 176 (3.41%) 7	3 / 176 (1.70%) 3	4 / 175 (2.29%) 4
Stomatitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 2	2 / 176 (1.14%) 2	5 / 175 (2.86%) 6
Constipation alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	2 / 176 (1.14%)	5 / 175 (2.86%)
occurrences (all)	2	2	5
Vomiting			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	7 / 176 (3.98%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	8	1	1
Abdominal discomfort			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 176 (1.70%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	3	1	1
Abdominal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	1	2	0
Dyspepsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	3 / 175 (1.71%)
occurrences (all)	0	1	3
Gastritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Toothache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	2 / 175 (1.14%)
occurrences (all)	1	1	2
Abdominal pain lower			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	2
Cheilitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1

Dental caries			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	1	0	2
Gingivitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	2 / 176 (1.14%)	0 / 175 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Colonic polyp			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Crohn's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Gingival bleeding			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Gingival hyperplasia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Gingival ulceration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Oral disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Oral pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Periodontal disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Reflux oesophagitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Salivary hypersecretion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0



Enteritis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Epigastric discomfort alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Gastritis atrophic alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Lip dry alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Aphthous ulcer alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Breath odour alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Chronic gastritis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Dysphagia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Enterocolitis alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Faeces soft			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Gingival hypertrophy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Glossitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Ileus paralytic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Lumbar hernia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Noninfective gingivitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Oral contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Peptic ulcer			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Salivary gland mucocoele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	2 / 176 (1.14%)	2 / 175 (1.14%)
occurrences (all)	2	2	2
Pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	4 / 175 (2.29%)
occurrences (all)	1	1	4
Eczema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	2	1	1
Dermatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	1	1	1
Urticaria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 176 (2.27%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	5	0	1
Heat rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Acne			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Blister			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Dermatitis allergic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Dry skin			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Eczema asteatotic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Pityriasis alba			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1

Rash erythematous alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Rash papular alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Rash pruritic alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Skin burning sensation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Skin erosion alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Skin ulcer alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	1 / 175 (0.57%) 1
Alopecia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	3 / 176 (1.70%) 3	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Night sweats alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Androgenetic alopecia alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Anhidrosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Fracture blisters			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Miliaria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Palmoplantar keratoderma alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Pigmentation disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Pruritus generalised alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Purpura alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Seborrhoeic dermatitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Skin discolouration alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Skin fissures alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Skin lesion alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Swelling face alternative dictionary used: MedDRA 21.1			



subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	1 / 175 (0.57%) 1
Bladder irritation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	1 / 175 (0.57%) 1
Calculus ureteric			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hypertonic bladder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Nephrolithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Neurogenic bladder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Nocturia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	1 / 176 (0.57%) 1	0 / 175 (0.00%) 0
Polyuria			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Haematuria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	2	0	0
Calculus urinary			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ketonuria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ureterolithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Urinary retention alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Endocrine disorders Autoimmune thyroiditis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Hypothyroidism alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0  0 / 176 (0.00%) 0	0 / 176 (0.00%) 0  0 / 176 (0.00%) 0	0 / 175 (0.00%) 0  0 / 175 (0.00%) 0
Musculoskeletal and connective tissue disorders Muscular weakness alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Back pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Myalgia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Arthralgia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Musculoskeletal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Musculoskeletal stiffness	0 / 176 (0.00%) 0  1 / 176 (0.57%) 1  2 / 176 (1.14%) 2  0 / 176 (0.00%) 0  1 / 176 (0.57%) 1	0 / 176 (0.00%) 0  1 / 176 (0.57%) 1  2 / 176 (1.14%) 2  0 / 176 (0.00%) 0  0 / 176 (0.00%) 0	4 / 175 (2.29%) 5  2 / 175 (1.14%) 3  0 / 175 (0.00%) 0  1 / 175 (0.57%) 1  1 / 175 (0.57%) 1

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	2	0	2
Monarthrititis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Myokymia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Flank pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	2	0	0
Neck pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 176 (1.14%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	2	0	0
Arthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Posture abnormal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

<p>Spinal osteoarthritis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 175 (0.00%)</p> <p>0</p>
<p>Spondylolisthesis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 175 (0.00%)</p> <p>0</p>
<p>Systemic lupus erythematosus</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 175 (0.00%)</p> <p>0</p>
<p>Tendonitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 176 (0.00%)</p> <p>0</p>	<p>0 / 175 (0.00%)</p> <p>0</p>
<p>Infections and infestations</p> <p>Periodontitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasopharyngitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Upper respiratory tract infection</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pharyngitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Influenza</p> <p>alternative dictionary used: MedDRA 21.1</p>	<p>1 / 176 (0.57%)</p> <p>1</p> <p>26 / 176 (14.77%)</p> <p>26</p> <p>8 / 176 (4.55%)</p> <p>9</p> <p>3 / 176 (1.70%)</p> <p>3</p>	<p>0 / 176 (0.00%)</p> <p>0</p> <p>23 / 176 (13.07%)</p> <p>23</p> <p>8 / 176 (4.55%)</p> <p>12</p> <p>1 / 176 (0.57%)</p> <p>2</p>	<p>0 / 175 (0.00%)</p> <p>0</p> <p>24 / 175 (13.71%)</p> <p>30</p> <p>14 / 175 (8.00%)</p> <p>17</p> <p>4 / 175 (2.29%)</p> <p>5</p>

subjects affected / exposed	2 / 176 (1.14%)	3 / 176 (1.70%)	1 / 175 (0.57%)
occurrences (all)	2	3	1
Gastroenteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	2 / 176 (1.14%)	2 / 175 (1.14%)
occurrences (all)	1	3	2
Tinea pedis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	0	1	1
Bronchitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	1	0	1
Gastroenteritis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	1 / 175 (0.57%)
occurrences (all)	0	1	1
Oral herpes			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Rhinitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Bacterial infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0

Herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Impetigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	1	0	1
Otitis externa			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Otitis media			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Purulence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	1	1	0
Sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Syphilis			
alternative dictionary used: MedDRA 21.1			



subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Viral infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Eczema infected			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 176 (0.57%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Angular cheilitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Bartholin's abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Candida infection			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Carbuncle			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Cystitis			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
alternative dictionary used:			
MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Ear infection			
alternative dictionary used:			
MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eczema impetiginous			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Eye infection bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Gingival abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Herpes dermatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Lung infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Mumps			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Paronychia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Pericoronitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Peritonsillar abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Pyoderma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Tinea manuum			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Varicella			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 176 (1.70%)	1 / 176 (0.57%)	5 / 175 (2.86%)
occurrences (all)	3	1	5
Hyponatraemia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	2 / 175 (1.14%)
occurrences (all)	0	1	2
Increased appetite			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2
Dyslipidaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Hyperlipidaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	3 / 175 (1.71%)
occurrences (all)	0	0	3
Diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2
Hypochloraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2
Dehydration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	1 / 176 (0.57%)	0 / 175 (0.00%)
occurrences (all)	0	1	0

Weight fluctuation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	1 / 175 (0.57%) 1
Appetite disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hyperglycaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 176 (0.57%) 1	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hyperammonaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hypercholesterolaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hypermagnesaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hyperuricaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hypoglycaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 176 (0.00%) 0	0 / 176 (0.00%) 0	0 / 175 (0.00%) 0
Hypoproteinaemia alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Obesity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 176 (0.00%)	0 / 176 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Core Phase: Perampanel 12 mg	Extension Phase: Perampanel 12 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	155 / 180 (86.11%)	618 / 679 (91.02%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Acrochordon			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Benign breast neoplasm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Benign hepatobiliary neoplasm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Leiomyoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Skin papilloma			
alternative dictionary used: MedDRA 21.1			



subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Uterine leiomyoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	3	
Vascular disorders			
Hypertension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)	
occurrences (all)	0	5	
Hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)	
occurrences (all)	1	2	
Angiodysplasia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)	
occurrences (all)	0	0	
Hyperaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Orthostatic hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Peripheral coldness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Phlebitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Surgical and medical procedures Tooth extraction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Wisdom teeth removal alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0  0 / 180 (0.00%) 0	1 / 679 (0.15%) 2  1 / 679 (0.15%) 1	
Pregnancy, puerperium and perinatal conditions Pregnancy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	2 / 679 (0.29%) 2	
General disorders and administration site conditions Irritability alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Fatigue alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Gait disturbance alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Pyrexia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Asthenia alternative dictionary used:	9 / 180 (5.00%) 9  9 / 180 (5.00%) 9  9 / 180 (5.00%) 9  4 / 180 (2.22%) 6	0 / 679 (0.00%) 0  34 / 679 (5.01%) 36  28 / 679 (4.12%) 34  39 / 679 (5.74%) 90	

MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	17 / 679 (2.50%)
occurrences (all)	3	20
Malaise		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	5
Feeling abnormal		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	6 / 679 (0.88%)
occurrences (all)	0	7
Face oedema		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Foreign body reaction		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Influenza like illness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	6
Oedema		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Chest discomfort		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	8 / 679 (1.18%)
occurrences (all)	0	9
Pain		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Chest pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Chills		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	2
Decreased activity		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Feeling hot		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Generalised oedema		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Oedema peripheral		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Peripheral swelling		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Thirst		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2

<p>Immune system disorders</p> <p>Allergy to arthropod sting</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Seasonal allergy</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p>	<p>4 / 679 (0.59%)</p> <p>4</p> <p>2 / 679 (0.29%)</p> <p>4</p>	
<p>Social circumstances</p> <p>Hearing aid user</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Reproductive system and breast disorders</p> <p>Prostatitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cervical cyst</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cervical polyp</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hypomenorrhoea</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Menorrhagia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p> <p>0 / 180 (0.00%)</p> <p>0</p> <p>1 / 180 (0.56%)</p> <p>1</p> <p>1 / 180 (0.56%)</p> <p>1</p> <p>0 / 180 (0.00%)</p> <p>0</p>	<p>2 / 679 (0.29%)</p> <p>2</p> <p>1 / 679 (0.15%)</p> <p>1</p> <p>1 / 679 (0.15%)</p> <p>1</p> <p>1 / 679 (0.15%)</p> <p>3</p>	

Menstrual disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Menstruation irregular		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	6
Pelvic fluid collection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Scrotal swelling		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)
occurrences (all)	1	0
Dysmenorrhoea		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	5
Amenorrhoea		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	2
Benign prostatic hyperplasia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Breast tenderness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Genital haemorrhage		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	3
Menopausal symptoms		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Menstruation delayed		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Oligomenorrhoea		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Ovarian cyst		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Pelvic pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Scrotal inflammation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Sexual dysfunction		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Vaginal discharge		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Laryngeal discomfort alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Epistaxis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Rhinitis allergic alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Upper respiratory tract inflammation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Cough alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Dyspnoea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Hiccups alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Productive cough alternative dictionary used:	2 / 180 (1.11%) 2  0 / 180 (0.00%) 0  1 / 180 (0.56%) 4  1 / 180 (0.56%) 1  0 / 180 (0.00%) 0  0 / 180 (0.00%) 0  0 / 180 (0.00%) 0  0 / 180 (0.00%) 0	13 / 679 (1.91%) 15  8 / 679 (1.18%) 10  5 / 679 (0.74%) 10  4 / 679 (0.59%) 4  9 / 679 (1.33%) 9  4 / 679 (0.59%) 6  1 / 679 (0.15%) 1	



MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Rhinorrhoea		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	9 / 679 (1.33%)
occurrences (all)	0	11
Sneezing		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Wheezing		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Asthma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Atelectasis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Dysphonia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Hyperventilation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	3
Laryngeal inflammation		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Nasal congestion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Oropharyngeal discomfort		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Pharyngeal inflammation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Pneumonia aspiration		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Respiratory tract congestion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Sputum increased		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Tonsillar inflammation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	2
Vasomotor rhinitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Psychiatric disorders			
Aggression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 180 (2.22%)	22 / 679 (3.24%)	
occurrences (all)	4	24	
Suicidal ideation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	21 / 679 (3.09%)	
occurrences (all)	2	28	
Anxiety			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	22 / 679 (3.24%)	
occurrences (all)	1	22	
Insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 180 (1.67%)	25 / 679 (3.68%)	
occurrences (all)	3	27	
Mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	12 / 679 (1.77%)	
occurrences (all)	0	13	
Anger			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 180 (1.67%)	9 / 679 (1.33%)	
occurrences (all)	3	9	
Depression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	16 / 679 (2.36%)	
occurrences (all)	2	19	
Affect lability			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	6 / 679 (0.88%)	
occurrences (all)	2	6	
Depressed mood			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	4
Abnormal behaviour		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	4
Hallucination, auditory		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Mood altered		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	4
Sleep disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	7 / 679 (1.03%)
occurrences (all)	0	8
Affective disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Agitation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	5 / 679 (0.74%)
occurrences (all)	1	6
Anxiety disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Confusional arousal		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2

Emotional disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Expressive language disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Fear		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Impatience		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Nervousness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	4
Obsessive-compulsive disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Personality change		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Personality disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Regressive behaviour		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Restlessness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Self-injurious ideation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Sleep talking		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Soliloquy		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Stubbornness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Suicide attempt		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	7 / 679 (1.03%)
occurrences (all)	1	7
Thinking abnormal		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Tic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Abnormal dreams		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Acute stress disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Intentional self-injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	2
Panic attack		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Bipolar disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Bruxism		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Confusional state		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Conversion disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Delusion		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Depressive symptom		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Dissociative disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Enuresis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Hallucination		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Impulsive behaviour		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Major depression		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Mania		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Mental disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2



Middle insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Mixed anxiety and depressive disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Neurosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Nightmare			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Panic disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Paranoia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Persecutory delusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Persistent depressive disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Psychogenic seizure			
alternative dictionary used: MedDRA 21.1			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Somatic symptom disorder</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Stress</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Suicidal behaviour</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p>	<p>4 / 679 (0.59%)</p> <p>4</p> <p>1 / 679 (0.15%)</p> <p>1</p> <p>1 / 679 (0.15%)</p> <p>1</p> <p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Product issues</p> <p>Device breakage</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Product blister packaging issue</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p> <p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Hepatobiliary disorders</p> <p>Hepatic function abnormal</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cholecystitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cholelithiasis</p> <p>alternative dictionary used: MedDRA 21.1</p>	<p>2 / 180 (1.11%)</p> <p>2</p> <p>0 / 180 (0.00%)</p> <p>0</p>	<p>6 / 679 (0.88%)</p> <p>6</p> <p>0 / 679 (0.00%)</p> <p>0</p>	

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Hepatic mass			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	2	
Hepatic steatosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Investigations			
Weight increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	6 / 180 (3.33%)	40 / 679 (5.89%)	
occurrences (all)	6	44	
Blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 180 (2.78%)	24 / 679 (3.53%)	
occurrences (all)	5	32	
Electrocardiogram QT prolonged			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 180 (2.22%)	9 / 679 (1.33%)	
occurrences (all)	4	13	
Blood phosphorus decreased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	9 / 679 (1.33%)	
occurrences (all)	2	10	
Protein urine present			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	12 / 679 (1.77%)	
occurrences (all)	1	14	
Weight decreased			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 180 (0.56%)	13 / 679 (1.91%)
occurrences (all)	1	14
Blood cholesterol increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	4
Blood uric acid increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	7 / 679 (1.03%)
occurrences (all)	0	7
Gamma-glutamyltransferase increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	5 / 679 (0.74%)
occurrences (all)	2	5
White blood cell count decreased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	4
Alanine aminotransferase increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Aspartate aminotransferase increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Blood parathyroid hormone abnormal alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Blood sodium decreased alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	6
Blood triglycerides abnormal alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Eosinophil count increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Monocyte count increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Neutrophil count decreased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Platelet count decreased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Red blood cells urine alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)
occurrences (all)	1	0
Urine ketone body present alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Vitamin D decreased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2

Blood glucose increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	0 / 679 (0.00%) 0	
Blood triglycerides increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	2 / 679 (0.29%) 2	
Blood urine present alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	3 / 679 (0.44%) 4	
Anticonvulsant drug level increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Blood bicarbonate decreased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Blood bilirubin increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Blood creatinine decreased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Blood lactate dehydrogenase increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Blood magnesium abnormal alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Blood phosphorus increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Blood pressure increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Blood sodium increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Gamma-glutamyltransferase abnormal alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Liver function test abnormal alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Liver function test increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Lymphocyte count decreased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Neutrophil count increased alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2

<p>Red blood cell count decreased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Red blood cells urine positive</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Thyroxine free decreased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Urine uric acid increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>White blood cell count increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>2 / 679 (0.29%)</p> <p>2</p>	
<p>pH urine increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Injury, poisoning and procedural complications</p> <p>Contusion</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Joint sprain</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Excoriation</p> <p>alternative dictionary used:</p>	<p>5 / 180 (2.78%)</p> <p>5</p> <p>3 / 180 (1.67%)</p> <p>3</p>	<p>49 / 679 (7.22%)</p> <p>81</p> <p>0 / 679 (0.00%)</p> <p>0</p>	



MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	0 / 679 (0.00%)
occurrences (all)	4	0
Foot fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	12 / 679 (1.77%)
occurrences (all)	2	13
Skin laceration		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	21 / 679 (3.09%)
occurrences (all)	2	21
Thermal burn		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	14 / 679 (2.06%)
occurrences (all)	2	15
Wound		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	8 / 679 (1.18%)
occurrences (all)	2	9
Animal bite		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	4 / 679 (0.59%)
occurrences (all)	2	4
Fall		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	14 / 679 (2.06%)
occurrences (all)	0	20
Head injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	11 / 679 (1.62%)
occurrences (all)	0	13
Limb injury		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	8 / 679 (1.18%)
occurrences (all)	0	8
Lip injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	4
Rib fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	5
Ankle fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	3
Arthropod sting		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	3
Burns second degree		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Heat stroke		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Joint dislocation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	4
Ligament rupture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2

Multiple injuries alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1	1 / 679 (0.15%) 1	
Periorbital haematoma alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	0 / 679 (0.00%) 0	
Radius fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	3 / 679 (0.44%) 3	
Road traffic accident alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1	1 / 679 (0.15%) 1	
Stab wound alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1	1 / 679 (0.15%) 1	
Sunburn alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Tibia fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Tooth fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	3 / 679 (0.44%) 3	
Tooth injury alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)
occurrences (all)	1	0
Wrist fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Forearm fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Scratch		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	4
Arthropod bite		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Bone contusion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Bone fissure		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Burns first degree		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Chemical poisoning		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Chest injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Chillblains		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	2
Clavicle fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Closed globe injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Concussion		
alternative dictionary used: MedDRA 21.11		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Compression fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Conjunctival abrasion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Ear canal abrasion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Eye contusion		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Eye injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Eyelid contusion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Eyelid injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Face injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	4
Fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Hand fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Heat illness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Joint injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Ligament injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Ligament sprain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	23 / 679 (3.39%)
occurrences (all)	0	24
Mouth injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Neck injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Patella fracture		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Post-traumatic neck syndrome		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Procedural pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Scar		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Skin abrasion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	16 / 679 (2.36%)
occurrences (all)	0	18
Skin injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Skin wound		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Soft tissue injury		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Subcutaneous haematoma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Subdural haematoma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Tooth dislocation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Toxicity to various agents		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1



Upper limb fracture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Congenital, familial and genetic disorders Hypophosphatasia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Cardiac disorders Angina pectoris alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Atrial fibrillation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Arteriosclerosis coronary artery alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Palpitations alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)  Tachycardia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0  0 / 180 (0.00%) 0  0 / 180 (0.00%) 0  0 / 180 (0.00%) 0  0 / 180 (0.00%) 0	2 / 679 (0.29%) 2  1 / 679 (0.15%) 1  1 / 679 (0.15%) 1  3 / 679 (0.44%) 4  1 / 679 (0.15%) 1	
Nervous system disorders Dizziness alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	76 / 180 (42.22%) 85	317 / 679 (46.69%) 435	

Somnolence		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	32 / 180 (17.78%)	165 / 679 (24.30%)
occurrences (all)	33	199
Headache		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	10 / 180 (5.56%)	94 / 679 (13.84%)
occurrences (all)	11	164
Ataxia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	7 / 180 (3.89%)	22 / 679 (3.24%)
occurrences (all)	8	26
Balance disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	4 / 180 (2.22%)	17 / 679 (2.50%)
occurrences (all)	4	18
Dysarthria		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	4 / 180 (2.22%)	22 / 679 (3.24%)
occurrences (all)	4	24
Hypoaesthesia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	12 / 679 (1.77%)
occurrences (all)	2	17
Tremor		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	3 / 180 (1.67%)	19 / 679 (2.80%)
occurrences (all)	3	23
Convulsion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	0 / 679 (0.00%)
occurrences (all)	2	0
Memory impairment		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	2 / 180 (1.11%)	14 / 679 (2.06%)
occurrences (all)	3	16
Nystagmus		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	4
Amnesia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	9 / 679 (1.33%)
occurrences (all)	0	9
Complex partial seizures		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Dementia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Lethargy		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	6 / 679 (0.88%)
occurrences (all)	0	6
Paraesthesia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	5
Aphasia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Clumsiness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2

Cranial nerve disorder alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1
Dizziness postural alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	2 / 679 (0.29%) 2
Dysaesthesia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	2 / 679 (0.29%) 2
Dyskinesia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1
Dystonia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1	1 / 679 (0.15%) 1
Head discomfort alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1
Hypersomnia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	5 / 679 (0.74%) 7
Migraine alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1	4 / 679 (0.59%) 4
Myoclonus alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Nerve root compression		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Psychomotor hyperactivity		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Sensory disturbance		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Anaesthesia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Dyslalia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	4
Grand mal convulsion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Partial seizures with secondary generalisation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	4
Syncope		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	6

Tongue biting			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	2	
Burning sensation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Carpal tunnel syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Cerebral disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Change in seizure presentation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Drooling			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Dysgeusia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Dysstasia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Epilepsy			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Focal dyscognitive seizures		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Hemiplegia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Hyposmia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Language disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Loss of consciousness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Neuralgia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Neuropathy peripheral		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Postictal headache		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Postural tremor			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Radial nerve palsy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	16 / 679 (2.36%)	
occurrences (all)	0	19	
Seizure cluster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	4	
Sleep deficit			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Slow response to stimuli			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Speech disorder			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)	
occurrences (all)	0	3	
Status epilepticus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Tonic convulsion			
alternative dictionary used: MedDRA 21.1			



<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Visual field defect</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Vocal cord paralysis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Blood and lymphatic system disorders</p> <p>Anaemia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 180 (1.11%)</p> <p>2</p>	<p>12 / 679 (1.77%)</p> <p>13</p>	
<p>Lymphadenitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>2 / 679 (0.29%)</p> <p>2</p>	
<p>Eosinophilia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p>	<p>3 / 679 (0.44%)</p> <p>3</p>	
<p>Iron deficiency anaemia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>3 / 679 (0.44%)</p> <p>3</p>	
<p>Leukopenia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p>	<p>3 / 679 (0.44%)</p> <p>3</p>	
<p>Neutropenia</p> <p>alternative dictionary used: MedDRA 21.1</p>			

subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)	
occurrences (all)	0	5	
Lymphopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	3	
Neutrophilia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	2	
Thrombocytopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Ear and labyrinth disorders			
Vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 180 (2.22%)	23 / 679 (3.39%)	
occurrences (all)	4	25	
Cerumen impaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Tinnitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	5 / 679 (0.74%)	
occurrences (all)	1	6	
Deafness neurosensory			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Ear pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	2	
Ear pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	2	
Hypoacusis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Motion sickness			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Sudden hearing loss			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Vertigo positional			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Eye disorders			
Vision blurred			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 180 (1.67%)	12 / 679 (1.77%)	
occurrences (all)	3	13	
Asthenopia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	3 / 679 (0.44%)	
occurrences (all)	2	3	
Conjunctivitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	2 / 180 (1.11%)	0 / 679 (0.00%)
occurrences (all)	2	0
Diplopia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	11 / 679 (1.62%)
occurrences (all)	1	12
Eyelid oedema		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Visual impairment		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	2 / 679 (0.29%)
occurrences (all)	2	2
Cataract		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Chalazion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	5
Conjunctival haemorrhage		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Dry eye		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	6
Dysmetropsia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Glaucoma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	2
Keratoconjunctivitis sicca		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)
occurrences (all)	1	0
Normal tension glaucoma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Retinal disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Vitreous floaters		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Eye pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Lacrimation increased		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Blepharitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Borderline glaucoma		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Conjunctival hyperaemia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Conjunctivitis allergic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	5
Corneal erosion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	2
Diabetic retinopathy		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Episcleritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Excessive eye blinking		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Eye discharge		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Eye pruritus		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Eyelid myoclonus		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Foreign body sensation in eyes		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Keratitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	4
Ocular hyperaemia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Psychogenic visual disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Punctate keratitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Swelling of eyelid		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Visual acuity reduced		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Xerophthalmia		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Gastrointestinal disorders			
Nausea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	10 / 180 (5.56%) 10	35 / 679 (5.15%) 37	
Diarrhoea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	6 / 180 (3.33%) 6	33 / 679 (4.86%) 42	
Stomatitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	3 / 180 (1.67%) 3	25 / 679 (3.68%) 35	
Constipation alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1	27 / 679 (3.98%) 36	
Vomiting alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	3 / 180 (1.67%) 3	24 / 679 (3.53%) 25	
Abdominal discomfort alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	2 / 180 (1.11%) 2	11 / 679 (1.62%) 13	
Abdominal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	2 / 180 (1.11%) 2	13 / 679 (1.91%) 15	
Dyspepsia alternative dictionary used: MedDRA 21.1			



subjects affected / exposed	0 / 180 (0.00%)	11 / 679 (1.62%)
occurrences (all)	0	11
Gastritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	7 / 679 (1.03%)
occurrences (all)	2	7
Toothache		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	10 / 679 (1.47%)
occurrences (all)	0	10
Abdominal pain lower		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	4
Cheilitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Dental caries		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	23 / 679 (3.39%)
occurrences (all)	0	25
Gingivitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	6 / 679 (0.88%)
occurrences (all)	0	6
Abdominal pain upper		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	8 / 679 (1.18%)
occurrences (all)	1	8
Aphthous stomatitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0

Colonic polyp		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Crohn's disease		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Gingival bleeding		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Gingival hyperplasia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Gingival pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Gingival ulceration		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	3
Haemorrhoids		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	4
Oral disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Oral pain		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Periodontal disease		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Reflux oesophagitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Salivary hypersecretion		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Dry mouth		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Enteritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Epigastric discomfort		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Gastritis atrophic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Lip dry		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0

Aphthous ulcer		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	7
Breath odour		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Chronic gastritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Dysphagia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Enterocolitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Faecaloma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Faeces soft		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Food poisoning		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Gastric ulcer		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Gastrooesophageal reflux disease		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	4
Gingival hypertrophy		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Glossitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Haemorrhoidal haemorrhage		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Ileus paralytic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Irritable bowel syndrome		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Large intestine polyp		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Lip ulceration		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Lumbar hernia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Noninfective gingivitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	2 / 679 (0.29%) 2	
Oesophagitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Oral contusion alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	2 / 679 (0.29%) 2	
Peptic ulcer alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Salivary gland mucocoele alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Skin and subcutaneous tissue disorders Rash alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	9 / 180 (5.00%) 9	31 / 679 (4.57%) 37	
Pruritus alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	2 / 180 (1.11%) 2	13 / 679 (1.91%) 16	
Eczema alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	2 / 180 (1.11%)	18 / 679 (2.65%)
occurrences (all)	2	20
Dermatitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	13 / 679 (1.91%)
occurrences (all)	1	13
Urticaria		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	8 / 679 (1.18%)
occurrences (all)	2	9
Heat rash		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)
occurrences (all)	1	0
Acne		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	7 / 679 (1.03%)
occurrences (all)	1	7
Blister		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Dermatitis allergic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Dermatitis atopic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	5 / 679 (0.74%)
occurrences (all)	1	9
Dermatitis contact		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	6 / 679 (0.88%)
occurrences (all)	1	7

Dry skin		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	6 / 679 (0.88%)
occurrences (all)	0	6
Eczema asteatotic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Erythema		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Pityriasis alba		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Rash erythematous		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Rash papular		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Rash pruritic		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Skin burning sensation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Skin erosion		
alternative dictionary used: MedDRA 21.1		



subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Skin ulcer		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Alopecia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Night sweats		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Androgenetic alopecia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Anhidrosis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Dermal cyst		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Drug eruption		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Fracture blisters		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Hyperkeratosis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Ingrowing nail		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Miliaria		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	4
Onychalgia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Palmoplantar keratoderma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Pigmentation disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Pruritus generalised		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Purpura		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Seborrhoeic dermatitis		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)	
occurrences (all)	0	3	
Skin discolouration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Skin fissures			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Skin lesion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Swelling face			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)	
occurrences (all)	1	4	
Bladder irritation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Calculus ureteric			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)	
occurrences (all)	1	0	
Hypertonic bladder			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Nephrolithiasis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Neurogenic bladder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	2 / 679 (0.29%)
occurrences (all)	1	2
Nocturia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Polyuria		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Proteinuria		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	6 / 679 (0.88%)
occurrences (all)	1	6
Urinary incontinence		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Haematuria		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Pollakiuria		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	5

<p>Calculus urinary</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Ketonuria</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Renal cyst</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Ureterolithiasis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Urinary retention</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Endocrine disorders</p> <p>Autoimmune thyroiditis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Hypothyroidism</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>	<p>1 / 679 (0.15%)</p> <p>1</p>	
<p>Musculoskeletal and connective tissue disorders</p> <p>Muscular weakness</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 180 (1.11%)</p> <p>2</p>	<p>6 / 679 (0.88%)</p> <p>7</p>	
<p>Back pain</p>			

alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	20 / 679 (2.95%)
occurrences (all)	2	22
Myalgia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	7 / 679 (1.03%)
occurrences (all)	1	7
Arthralgia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	10 / 679 (1.47%)
occurrences (all)	1	13
Musculoskeletal pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	9 / 679 (1.33%)
occurrences (all)	1	9
Musculoskeletal stiffness		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	5 / 679 (0.74%)
occurrences (all)	2	6
Pain in extremity		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	14 / 679 (2.06%)
occurrences (all)	0	15
Monarthritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	0 / 679 (0.00%)
occurrences (all)	1	0
Muscle spasms		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Muscle twitching		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Musculoskeletal chest pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	4
Myokymia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Tenosynovitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Flank pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Neck pain		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Osteoarthritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Arthritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Joint swelling		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Muscle tightness alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Osteoporosis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	3 / 679 (0.44%) 3	
Periarthritis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Posture abnormal alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Spinal osteoarthritis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Spondylolisthesis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Systemic lupus erythematosus alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Tendonitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0	1 / 679 (0.15%) 1	
Infections and infestations			



Periodontitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	5
Nasopharyngitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	23 / 180 (12.78%)	170 / 679 (25.04%)
occurrences (all)	28	325
Upper respiratory tract infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	11 / 180 (6.11%)	70 / 679 (10.31%)
occurrences (all)	19	147
Pharyngitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	24 / 679 (3.53%)
occurrences (all)	2	36
Influenza		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	2 / 180 (1.11%)	31 / 679 (4.57%)
occurrences (all)	2	36
Gastroenteritis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	18 / 679 (2.65%)
occurrences (all)	1	20
Tinea pedis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	8 / 679 (1.18%)
occurrences (all)	1	9
Bronchitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	7 / 679 (1.03%)
occurrences (all)	1	7
Gastroenteritis viral		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	3
Oral herpes		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	4 / 679 (0.59%)
occurrences (all)	1	5
Rhinitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	12 / 679 (1.77%)
occurrences (all)	1	13
Bacterial infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Gastroenteritis bacterial		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Herpes zoster		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Impetigo		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Otitis externa		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	8 / 679 (1.18%)
occurrences (all)	0	10
Otitis media		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	5

Pneumonia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	7 / 679 (1.03%)
occurrences (all)	1	7
Purulence		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Respiratory tract infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Sinusitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	3 / 679 (0.44%)
occurrences (all)	1	3
Syphilis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Tonsillitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	1 / 180 (0.56%)	6 / 679 (0.88%)
occurrences (all)	1	8
Urinary tract infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	8 / 679 (1.18%)
occurrences (all)	0	10
Viral infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Wound infection		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	1 / 180 (0.56%)	1 / 679 (0.15%)
occurrences (all)	1	1
Eczema infected		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Onychomycosis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Angular cheilitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Bartholin's abscess		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Candida infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Carbuncle		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Cellulitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Chronic sinusitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Conjunctivitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	11 / 679 (1.62%)
occurrences (all)	0	12
Cystitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Dermatophytosis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Dermatophytosis of nail		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Ear infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Eczema impetiginous		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Enteritis infectious		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Eye infection bacterial		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Folliculitis		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Fungal infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Fungal skin infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	3
Gingival abscess		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Helicobacter infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Herpes dermatitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Hordeolum		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	2
Infected dermal cyst		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Kidney infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Lung infection		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Mumps		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Oral candidiasis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Paronychia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Pericoronitis		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Peritonsillar abscess		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Pyoderma		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Tinea manuum		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Vaginal infection		
alternative dictionary used: MedDRA 21.1		

subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)	
occurrences (all)	0	3	
Varicella			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Vulvovaginitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Decreased appetite			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 180 (1.67%)	21 / 679 (3.09%)	
occurrences (all)	3	21	
Hyponatraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	10 / 679 (1.47%)	
occurrences (all)	2	12	
Increased appetite			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 180 (1.67%)	6 / 679 (0.88%)	
occurrences (all)	3	6	
Dyslipidaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 180 (1.11%)	6 / 679 (0.88%)	
occurrences (all)	2	6	
Hyperlipidaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	7 / 679 (1.03%)	
occurrences (all)	0	8	
Diabetes mellitus			
alternative dictionary used: MedDRA 21.1			



subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Hypochloraemia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)
occurrences (all)	0	4
Dehydration		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Hypertriglyceridaemia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)
occurrences (all)	0	7
Hypokalaemia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)
occurrences (all)	0	3
Weight fluctuation		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1
Appetite disorder		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	0 / 679 (0.00%)
occurrences (all)	0	0
Hyperglycaemia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	4 / 679 (0.59%)
occurrences (all)	0	5
Hyperammonaemia		
alternative dictionary used: MedDRA 21.1		
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)
occurrences (all)	0	1

Hypercholesterolaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	3 / 679 (0.44%)	
occurrences (all)	0	4	
Hypermagnesaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	2	
Hyperuricaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	5 / 679 (0.74%)	
occurrences (all)	0	6	
Hypoglycaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	2 / 679 (0.29%)	
occurrences (all)	0	6	
Hypoproteinaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	
Obesity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 180 (0.00%)	1 / 679 (0.15%)	
occurrences (all)	0	1	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 March 2012	Amendment 01: Inclusion/Exclusion criteria was updated as per amendment 01 dated 19 March 2012.
09 November 2012	Amendment 02: <ul style="list-style-type: none"><li>- Increased the number of sites and added Oceania as a region for conducting the study.</li><li>- Specified that it was not required to obtain a written or verbal assent from subjects with severe mental retardation.</li><li>- Modified the mode of administration of study drug to allow for study drug to be taken without food before bedtime.</li><li>- Specified that subjects should not increase or decrease their dose more than once unless there was a significant medical reason.</li></ul>
16 April 2013	Amendment 03: No major changes were made to the protocol Version 4.0 (Amendment 03) dated 16 April 2013.
05 November 2014	Amendment 04: <ul style="list-style-type: none"><li>- Clarified that, depending on the requirements in each country, the Maintenance Period of the Extension Phase was terminated within 3 months from the market launch date of perampanel in that country or at Week 75, whichever is later.</li><li>- Clarified that the Follow-up Visit was not required if the study drug was switched to the commercial product for perampanel.</li></ul>
28 May 2015	Amendment 05: Specified the schedule of procedures/assessments separately for subjects whose visit exceeded Week 75 in the Extension Phase because some assessments were deemed unnecessary for evaluation, per sponsor's decision.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported