



## Clinical trial results:

### **Efficacy and safety of eslicarbazepine acetate (BIA 2-093) as monotherapy for patients with newly diagnosed partial-onset seizures: a double-blind, randomized, active-controlled, parallel-group, multicenter clinical study**

#### **Summary**

EudraCT number	2009-011135-13
Trial protocol	DE IE AT FI LT PT GB SK ES IT CZ LV BE EE HU BG
Global end of trial date	08 September 2016

#### **Results information**

Result version number	v1 (current)
This version publication date	24 September 2017
First version publication date	24 September 2017
Summary attachment (see zip file)	bia-2093-311 (bia-2093-311_STUDY SYNOPSIS-03-apr-2017.pdf)

#### **Trial information**

##### **Trial identification**

Sponsor protocol code	BIA-2093-311
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##### **Additional study identifiers**

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

Notes:

##### **Sponsors**

Sponsor organisation name	BIAL - Portela & CA, S.A.
Sponsor organisation address	À Av. Siderurgia Nacional, Coronado, Portugal, 4745-457
Public contact	André Garrido, BIAL - Portela & C <sup>a</sup> , S.A., 00351 229866100, andre.garrido@bial.com
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Notes:

##### **Paediatric regulatory details**

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 July 2015
Global end of trial reached?	Yes
Global end of trial date	08 September 2016
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Primary: To demonstrate that monotherapy with eslicarbazepine acetate (ESL; 800 to 1600 mg once daily [QD]) is not inferior to monotherapy with controlled-release carbamazepine (CBZ-CR; 200 to 600 mg twice daily [BID]) in adults ( $\geq 18$  years) with newly diagnosed epilepsy experiencing partial-onset seizures.

Protection of trial subjects:

The trial was conducted in accordance with the International Conference on Harmonisation (ICH), Good Clinical Practices (GCP), Good Manufacturing Practice (GMP), the ethical principles of the Declaration of Helsinki and with applicable local regulations. This trial was conducted by qualified persons who respected the rights and welfare of the subjects and after the review and approval of the protocol by IEC.

Background therapy:

Concomitant AED therapy (1 or 2 AEDs).

Evidence for comparator: -

Actual start date of recruitment	27 January 2011
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	Argentina: 35
Country: Number of subjects enrolled	Australia: 23
Country: Number of subjects enrolled	Austria: 13
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Bulgaria: 54
Country: Number of subjects enrolled	Brazil: 26
Country: Number of subjects enrolled	Chile: 16
Country: Number of subjects enrolled	Czech Republic: 42
Country: Number of subjects enrolled	Germany: 27
Country: Number of subjects enrolled	Spain: 35
Country: Number of subjects enrolled	Estonia: 11
Country: Number of subjects enrolled	Finland: 36
Country: Number of subjects enrolled	France: 12
Country: Number of subjects enrolled	United Kingdom: 30
Country: Number of subjects enrolled	Croatia: 6
Country: Number of subjects enrolled	Hungary: 40

Country: Number of subjects enrolled	India: 67
Country: Number of subjects enrolled	Ireland: 8
Country: Number of subjects enrolled	Israel: 11
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Lithuania: 5
Country: Number of subjects enrolled	Latvia: 28
Country: Number of subjects enrolled	Peru: 13
Country: Number of subjects enrolled	Poland: 9
Country: Number of subjects enrolled	Portugal: 17
Country: Number of subjects enrolled	Romania: 44
Country: Number of subjects enrolled	Russian Federation: 104
Country: Number of subjects enrolled	Serbia: 21
Country: Number of subjects enrolled	Slovakia: 20
Country: Number of subjects enrolled	Sweden: 13
Country: Number of subjects enrolled	Ukraine: 43
Worldwide total number of subjects	815
EEA total number of subjects	456

Notes:

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### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	753
From 65 to 84 years	61
85 years and over	1

## Subject disposition

### Recruitment

Recruitment details:

The patient recruitment period lasted 41 months. First subject was recruited on 27JAN2011, the last subject on 09JUN2014.

### Pre-assignment

Screening details:

Subjects who met all the inclusion criteria and none of the exclusion criteria. 929 subjects were enrolled to the trial and 114 subjects were screening failures including 36 who met all the inclusion criteria and none of the exclusion criteria but were not randomised. 2 subjects were randomised but not treated.

### Pre-assignment period milestones

Number of subjects started	929 <sup>[1]</sup>
Number of subjects completed	813 <sup>[2]</sup>

### Pre-assignment subject non-completion reasons

Reason: Number of subjects	Adverse event, non-fatal: 1
Reason: Number of subjects	Consent withdrawn by subject: 25
Reason: Number of subjects	Pregnancy: 1
Reason: Number of subjects	Ineligibility: 72
Reason: Number of subjects	Subject's non compliance: 2
Reason: Number of subjects	Sponsor's discretion: 3
Reason: Number of subjects	Progressive disease: 1
Reason: Number of subjects	Randomised, but not treated: 2
Reason: Number of subjects	Other reason: 9

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number of subjects reported to have started the pre-assignment period is the number of enrolled subjects; The worldwide number of subjects enrolled in the trial is number of randomised subjects. 2 randomised subjects were not treated.

[2] - The number of subjects reported to be in the pre-assignment period is not consistent with the number starting period 1. It is expected that the number completing the pre-assignment period are also present in the arms in period 1.

Justification: The arms are not mutually exclusive and number starting period 1 should be calculated as sum of the Eslicarbazepine acetate and CBZ-CR or as sum of ESL 800 mg QD, ESL 1200 mg QD, ESL 1600 mg QD, CBZ-CR 200 mg BID, CBZ-CR 400 mg BID, CBZ-CR 600 mg BID and not as sum of all arms groups. Therefore, the number of subjects starting period 1 consist with the number of subjects completing the pre-assignment period.

### Period 1

Period 1 title	DOUBLE-BLIND TREATMENT (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

### Arms

Are arms mutually exclusive?	No
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<b>Arm title</b>	Eslicarbazepine acetate
Arm description: Patients will receive the study treatment in the form of 400-800 mg Eslicarbazepine Acetate capsules. The study treatment should be administered once daily. The maximum absolute daily dosage will be 1600 mg.	
Arm type	Experimental
Investigational medicinal product name	Eslicarbazepine acetate
Investigational medicinal product code	BIA 2-093
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: The study treatment should be administered once daily in the evening. The maximum absolute dosage will be 1600 mg once daily.	
Dose Level A0 (during Titration Period): ESL 400 mg once daily Dose Level A: ESL 800 mg once daily Dose Level B0 (during Titration Period): ESL 1200 mg once daily Dose Level B: ESL 1200 mg once daily Dose Level C0 (during Titration Period): ESL 1600 mg once daily Dose Level C: ESL 1600 mg once daily	
<b>Arm title</b>	CBZ-CR
Arm description: Patients will receive the study treatment in the form of 200-400 mg Carbamazepine controlled-release (Tegretal®-CR) capsules. The study treatment should be administered twice daily. The maximum absolute daily dosage will be 1200 mg. Carbatrol-XR (100 mg) capsules will be used during the 1-week Titration Period, when needed, because Tegretal-CR does not have a 100 mg capsule.	
Arm type	Active comparator
Investigational medicinal product name	Carbamazepine controlled-release
Investigational medicinal product code	
Other name	Tegretal®-CR, Carbatrol®-XR
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: The study treatment should be administered twice daily in the morning and in the evening except for Dose Level A0 where morning dose is Placebo. The maximum absolute daily dosage will be 1200 mg.	
Dose Level A0 (during Titration Period): CBZ-CR 200 mg once daily Dose Level A: CBZ-CR 200 mg twice daily Dose Level B0 (during Titration Period): CBZ-CR 300 mg twice daily Dose Level B: CBZ-CR 400 mg twice daily Dose Level C0 (during Titration Period): CBZ-CR 500 mg twice daily Dose Level C: CBZ-CR 600 mg twice daily	
<b>Arm title</b>	ESL 800 mg QD
Arm description: Patients with last evaluated dose 800 mg QD of Eslicarbazepine Acetate.	
Arm type	Experimental
Investigational medicinal product name	Eslicarbazepine acetate
Investigational medicinal product code	BIA 2-093
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: The study treatment should be administered once daily in the evening.	
<b>Arm title</b>	ESL 1200 mg QD

Arm description:	
Patients with last evaluated dose 1200 mg QD of Eslicarbazepine Acetate.	
Arm type	Experimental
Investigational medicinal product name	Eslicarbazepine acetate
Investigational medicinal product code	BIA 2-093
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
The study treatment should be administered once daily in the evening.	
<b>Arm title</b>	ESL 1600 mg QD
Arm description:	
Patients with last evaluated dose 1600 mg QD of Eslicarbazepine Acetate.	
Arm type	Experimental
Investigational medicinal product name	Eslicarbazepine acetate
Investigational medicinal product code	BIA 2-093
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
The study treatment should be administered once daily in the evening.	
<b>Arm title</b>	CBZ-CR 200 mg BID
Arm description:	
Patients with last evaluated dose 200 mg BID of Carbamazepine controlled-release.	
Arm type	Active comparator
Investigational medicinal product name	Carbamazepine controlled-release
Investigational medicinal product code	
Other name	Tegretal®-CR
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
The study treatment should be administered twice daily in the morning and in the evening.	
<b>Arm title</b>	CBZ-CR 400 mg BID
Arm description:	
Patients with last evaluated dose 400 mg BID of Carbamazepine controlled-release.	
Arm type	Active comparator
Investigational medicinal product name	Carbamazepine controlled-release
Investigational medicinal product code	
Other name	Tegretal®-CR
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
The study treatment should be administered twice daily in the morning and in the evening.	
<b>Arm title</b>	CBZ-CR 600 mg BID
Arm description:	
Patients with last evaluated dose 600 mg BID of Carbamazepine controlled-release.	
Arm type	Active comparator

Investigational medicinal product name	Carbamazepine controlled-release
Investigational medicinal product code	
Other name	Tegretal®-CR
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

The study treatment should be administered twice daily in the morning and in the evening.

Number of subjects in period 1	Eslicarbazepine acetate	CBZ-CR	ESL 800 mg QD
Started	401	412	271
Completed	132	148	103
Not completed	269	264	168
Adverse event, serious fatal	2	2	2
Other reason	46	67	35
Adverse event, serious non-fatal	7	12	3
Ineligibility	1	1	1
Consent withdrawn by subject	55	41	44
Investigator or sponsor discretion	10	12	7
Subject non compliance	10	14	8
Adverse event, non-fatal	32	48	21
Pregnancy	7	4	2
Progressive disease	5	6	3
Unblinding of the IMP	1	1	1
Lack of efficacy	90	56	38
Protocol deviation	3	-	3

Number of subjects in period 1	ESL 1200 mg QD	ESL 1600 mg QD	CBZ-CR 200 mg BID
Started	70	60	317
Completed	21	8	114
Not completed	49	52	203
Adverse event, serious fatal	-	-	2
Other reason	8	3	59
Adverse event, serious non-fatal	3	1	11
Ineligibility	-	-	1
Consent withdrawn by subject	8	3	35
Investigator or sponsor discretion	2	1	9
Subject non compliance	2	-	10
Adverse event, non-fatal	9	2	36
Pregnancy	2	3	3
Progressive disease	1	1	6

Unblinding of the IMP	-	-	1
Lack of efficacy	14	38	30
Protocol deviation	-	-	-

<b>Number of subjects in period 1</b>	CBZ-CR 400 mg BID	CBZ-CR 600 mg BID
Started	61	34
Completed	25	9
Not completed	36	25
Adverse event, serious fatal	-	-
Other reason	7	1
Adverse event, serious non-fatal	1	-
Ineligibility	-	-
Consent withdrawn by subject	5	1
Investigator or sponsor discretion	3	-
Subject non compliance	2	2
Adverse event, non-fatal	8	4
Pregnancy	1	-
Progressive disease	-	-
Unblinding of the IMP	-	-
Lack of efficacy	9	17
Protocol deviation	-	-



## Baseline characteristics

### Reporting groups<sup>[1]</sup>

Reporting group title	Eslicarbazepine acetate
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Reporting group description:

Patients will receive the study treatment in the form of 400-800 mg Eslicarbazepine Acetate capsules. The study treatment should be administered once daily. The maximum absolute daily dosage will be 1600 mg.

Reporting group title	CBZ-CR
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Reporting group description:

Patients will receive the study treatment in the form of 200-400 mg Carbamazepine controlled-release (Tegretal®-CR) capsules. The study treatment should be administered twice daily. The maximum absolute daily dosage will be 1200 mg. Carbatrol-XR (100 mg) capsules will be used during the 1-week Titration Period, when needed, because Tegretal-CR does not have a 100 mg capsule.

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number reported to be in the baseline period is the number of treated subjects; The worldwide number of subjects enrolled in the trial is number of randomised subjects. Baseline period does not include 2 subjects who were randomised but not treated.

Reporting group values	Eslicarbazepine acetate	CBZ-CR	Total
Number of subjects	401	412	813
Age Categorical			
Age Categorical Characteristic			
Units: Subjects			
In Utero	0	0	0
Preterm newborn- gestational age < 37 wk	0	0	0
Newborns (0-27days)	0	0	0
Infants and toddlers (28days - 23months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 year)	0	0	0
From 18 - 64 years	374	377	751
From 65 - 84 years	26	35	61
Over 85 years	1	0	1
Age Continuous			
Age Continuous Characteristic			
Units: Years			
arithmetic mean	37.6	38.7	
standard deviation	± 15.79	± 16.29	-
Gender Categorical			
Gender Categorical Characteristic			
Units: Subjects			
Female	173	192	365
Male	228	220	448

## End points

### End points reporting groups

Reporting group title	Eslicarbazepine acetate
Reporting group description: Patients will receive the study treatment in the form of 400-800 mg Eslicarbazepine Acetate capsules. The study treatment should be administered once daily. The maximum absolute daily dosage will be 1600 mg.	
Reporting group title	CBZ-CR
Reporting group description: Patients will receive the study treatment in the form of 200-400 mg Carbamazepine controlled-release (Tegretal®-CR) capsules. The study treatment should be administered twice daily. The maximum absolute daily dosage will be 1200 mg. Carbatrol-XR (100 mg) capsules will be used during the 1-week Titration Period, when needed, because Tegretal-CR does not have a 100 mg capsule.	
Reporting group title	ESL 800 mg QD
Reporting group description: Patients with last evaluated dose 800 mg QD of Eslicarbazepine Acetate.	
Reporting group title	ESL 1200 mg QD
Reporting group description: Patients with last evaluated dose 1200 mg QD of Eslicarbazepine Acetate.	
Reporting group title	ESL 1600 mg QD
Reporting group description: Patients with last evaluated dose 1600 mg QD of Eslicarbazepine Acetate.	
Reporting group title	CBZ-CR 200 mg BID
Reporting group description: Patients with last evaluated dose 200 mg BID of Carbamazepine controlled-release.	
Reporting group title	CBZ-CR 400 mg BID
Reporting group description: Patients with last evaluated dose 400 mg BID of Carbamazepine controlled-release.	
Reporting group title	CBZ-CR 600 mg BID
Reporting group description: Patients with last evaluated dose 600 mg BID of Carbamazepine controlled-release.	
Subject analysis set title	ESL x Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All patients who received at least one dose of study treatment.	
Subject analysis set title	CBZ-CR x Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All patients who received at least one dose of study treatment.	
Subject analysis set title	ESL 800 mg QD x Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All patients who received at least one dose of study treatment and the last evaluated dose was 800 mg QD of Eslicarbazepine Acetate.	
Subject analysis set title	ESL 1200 mg QD x Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All patients who received at least one dose of study treatment and the last evaluated dose was 1200 mg QD of Eslicarbazepine Acetate.	
Subject analysis set title	ESL 1600 mg QD x Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who received at least one dose of study treatment and the last evaluated dose was 1600 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	CBZ-CR 200 mg BID x Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who received at least one dose of study treatment and the last evaluated dose was 200 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 400 mg BID x Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who received at least one dose of study treatment and the last evaluated dose was 400 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 600 mg BID x Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who received at least one dose of study treatment and the last evaluated dose was 600 mg BID of Carbamazepine controlled-release.

Subject analysis set title	ESL x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients randomised and treated with at least one dose of study treatment after randomisation.

Subject analysis set title	CBZ-CR x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients randomised and treated with at least one dose of study treatment after randomisation.

Subject analysis set title	ESL 800 mg QD x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients randomised and treated with at least one dose of study treatment after randomisation and the last evaluated dose was 800 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1200 mg QD x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients randomised and treated with at least one dose of study treatment after randomisation and the last evaluated dose was 1200 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1600 mg QD x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients who received at least one dose of study treatment and the last evaluated dose was 1600 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	CBZ-CR 200 mg BID x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients randomised and treated with at least one dose of study treatment after randomisation and the last evaluated dose was 200 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 400 mg BID x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients randomised and treated with at least one dose of study treatment after randomisation and the last evaluated dose was 400 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 600 mg BID x Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All patients randomised and treated with at least one dose of study treatment after randomisation and

the last evaluated dose was 600 mg BID of Carbamazepine controlled-release.

Subject analysis set title	ESL x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations

Subject analysis set title	CBZ-CR x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations

Subject analysis set title	ESL 800 mg QD x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations and the last evaluated dose was 800 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1200 mg QD x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations and the last evaluated dose was 1200 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1600 mg QD x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations and the last evaluated dose was 1600 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	CBZ-CR 200 mg BID x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations and the last evaluated dose was 200 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 400 mg BID x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations and the last evaluated dose was 400 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 600 mg BID x Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the FAS without any major protocol deviations and the last evaluated dose was 600 mg BID of Carbamazepine controlled-release.

Subject analysis set title	ESL x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis.

Subject analysis set title	CBZ-CR x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis.

Subject analysis set title	ESL 800 mg QD x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 800 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1200 mg QD x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 1200 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1600 mg QD x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 1600 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	CBZ-CR 200 mg BID x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 200 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 400 mg BID x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 400 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 600 mg BID x Corrected Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

PPS based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 600 mg BID of Carbamazepine controlled-release.

Subject analysis set title	ESL x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy.

Subject analysis set title	CBZ-CR x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy.

Subject analysis set title	ESL 800 mg QD x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy and the last evaluated dose was 800 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1200 mg QD x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy and the last evaluated dose was 1200 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1600 mg QD x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy and the last evaluated dose was 1600 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	CBZ-CR 200 mg BID x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy and the last evaluated dose was 200

mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 400 mg BID x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy and the last evaluated dose was 400 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 600 mg BID x Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

All patients of the PP Set excluding all subjects discontinuing the study before reaching the end of the 26-week Evaluation Period for any reasons not linked to efficacy and the last evaluated dose was 600 mg BID of Carbamazepine controlled-release.

Subject analysis set title	ESL x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis.

Subject analysis set title	CBZ-CR x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis.

Subject analysis set title	ESL 800 mg QD x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 800 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1200 mg QD x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 1200 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	ESL 1600 mg QD x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 1600 mg QD of Eslicarbazepine Acetate.

Subject analysis set title	CBZ-CR 200 mg BID x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 200 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 400 mg BID x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 400 mg BID of Carbamazepine controlled-release.

Subject analysis set title	CBZ-CR 600 mg BID x Corrected Per Protocol Subset
Subject analysis set type	Per protocol

Subject analysis set description:

Per Protocol Subset (SPP) based on data corrections identified after the snapshot for the primary statistical analysis and the last evaluated dose for patient was 600 mg BID of Carbamazepine controlled-release.

**Primary: Seizure freedom**

End point title	Seizure freedom
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End point description:

Proportion of subjects who are seizure free (seizure freedom) for the entire 26-week Evaluation Period (ESD 182) at the last evaluated dose level.

End point type	Primary
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End point timeframe:

26-week Evaluation Period of the last evaluated dose level

End point values	ESL x Full Analysis Set	CBZ-CR x Full Analysis Set	ESL x Per Protocol Set	CBZ-CR x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	401	412	388	397
Units: Subjects				
number (not applicable)				
Western Europe	46	57	44	55
Central Europe	62	67	62	65
Eastern Europe	58	68	57	67
Russia	45	46	44	46
GBR+Ireland+Australia	18	16	17	16
South America	30	24	29	24
India	25	27	23	27
Total	284	305	276	300

End point values	ESL x Corrected Per Protocol Set	CBZ-CR x Corrected Per Protocol Set	ESL x Per Protocol Subset	CBZ-CR x Per Protocol Subset
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	389	397	316	326
Units: Subjects				
number (not applicable)				
Western Europe	44	55	44	55
Central Europe	62	65	62	65
Eastern Europe	57	67	57	67
Russia	44	46	44	46
GBR+Ireland+Australia	17	16	17	16
South America	29	24	29	24
India	24	27	23	27
Total	277	300	276	300

End point values	ESL x Corrected Per Protocol Subset	CBZ-CR x Corrected Per Protocol Subset		
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Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	317	326		
Units: Subjects				
number (not applicable)				
Western Europe	44	55		
Central Europe	62	65		
Eastern Europe	57	67		
Russia	44	46		
GBR+Ireland+Australia	17	16		
South America	29	24		
India	24	27		
Total	277	300		

## Statistical analyses

<b>Statistical analysis title</b>	Average risk difference PP
Statistical analysis description:	
The difference in proportions stratified by region estimated by the average risk difference (ARD) over the different regions and estimated from the coefficients of the logistic regression.	
Comparison groups	ESL x Per Protocol Set v CBZ-CR x Per Protocol Set
Number of subjects included in analysis	785
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[1]</sup>
Method	P-value was not provided
Parameter estimate	Average Risk Difference (ARD)
Point estimate	-4.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	1.74

Notes:

[1] - Non-inferiority margin = -12%

<b>Statistical analysis title</b>	Average risk difference FAS
Statistical analysis description:	
The difference in proportions stratified by region estimated by the average risk difference (ARD) over the different regions and estimated from the coefficients of the logistic regression.	
Comparison groups	ESL x Full Analysis Set v CBZ-CR x Full Analysis Set
Number of subjects included in analysis	813
Analysis specification	Pre-specified
Analysis type	superiority <sup>[2]</sup>
Method	P-value was not provided
Parameter estimate	Average Risk Difference (ARD)
Point estimate	-3.07



Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.04
upper limit	2.89

Notes:

[2] - ESL is assumed to be superior to CBZ-CR if the lower limit of the CI > 0%

<b>Statistical analysis title</b>	Average risk difference SPP
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Statistical analysis description:

The difference in proportions stratified by region estimated by the average risk difference (ARD) over the different regions and estimated from the coefficients of the logistic regression.

Comparison groups	ESL x Per Protocol Subset v CBZ-CR x Per Protocol Subset
Number of subjects included in analysis	642
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[3]</sup>
Method	P-value was not provided
Parameter estimate	Average Risk Difference (ARD)
Point estimate	-4.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.13
upper limit	0.1

Notes:

[3] - Non-inferiority margin = -12%

<b>Statistical analysis title</b>	Average risk difference PPcor
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Statistical analysis description:

The difference in proportions stratified by region estimated by the average risk difference (ARD) over the different regions and estimated from the coefficients of the logistic regression.

Comparison groups	ESL x Corrected Per Protocol Set v CBZ-CR x Corrected Per Protocol Set
Number of subjects included in analysis	786
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[4]</sup>
Method	P-value was not provided
Parameter estimate	Average Risk Difference (ARD)
Point estimate	-4.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.23
upper limit	1.8

Notes:

[4] - Non-inferiority margin = -12%

<b>Statistical analysis title</b>	Average risk difference SPPcor
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Statistical analysis description:

The difference in proportions stratified by region estimated by the average risk difference (ARD) over the different regions and estimated from the coefficients of the logistic regression.

Comparison groups	ESL x Corrected Per Protocol Subset v CBZ-CR x Corrected Per Protocol Subset
Number of subjects included in analysis	643
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[5]</sup>
Method	P-value was not provided
Parameter estimate	Average Risk Difference (ARD)
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	0.11

Notes:

[5] - Non-inferiority margin = -12%

## Secondary: 1-year treatment effect

End point title	1-year treatment effect
End point description:	The proportion of seizure-free subjects during 1 year of treatment at the last evaluated dose
End point type	Secondary
End point timeframe:	1 year after first day of Evaluation period

End point values	ESL x Full Analysis Set	CBZ-CR x Full Analysis Set	ESL x Per Protocol Set	CBZ-CR x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	401	412	388	397
Units: Subjects				
number (not applicable)				
Western Europe	40	55	38	54
Central Europe	58	62	58	60
Eastern Europe	56	58	55	57
Russia	38	43	37	43
GBR+Ireland+Australia	15	15	15	15
South America	26	23	26	23
India	23	27	22	27
Total	256	283	251	279

## Statistical analyses

Statistical analysis title	Average risk difference PP
Statistical analysis description:	The difference in proportions stratified by region estimated by the average risk difference (ARD) over the different regions and estimated from the coefficients of the logistic regression.
Comparison groups	ESL x Per Protocol Set v CBZ-CR x Per Protocol Set

Number of subjects included in analysis	785
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[6]</sup>
Method	P-value was not provided
Parameter estimate	Average Risk Difference (ARD)
Point estimate	-5.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.88
upper limit	0.97

Notes:

[6] - Non-inferiority margin = -12%

<b>Statistical analysis title</b>	Average risk difference FAS
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Statistical analysis description:

The difference in proportions stratified by region estimated by the average risk difference (ARD) over the different regions and estimated from the coefficients of the logistic regression.

Comparison groups	ESL x Full Analysis Set v CBZ-CR x Full Analysis Set
Number of subjects included in analysis	813
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[7]</sup>
Method	P-value was not provided
Parameter estimate	Average Risk Difference (ARD)
Point estimate	-4.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.07
upper limit	1.64

Notes:

[7] - Non-inferiority margin = -12%

## Secondary: Treatment failure time

End point title	Treatment failure time
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End point description:

The time to first seizure at the last evaluated dose.

End point type	Secondary
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End point timeframe:

From the first day of Evaluation period till the last IMP intake of the target dose + 1 day

End point values	ESL x Full Analysis Set	CBZ-CR x Full Analysis Set	ESL x Per Protocol Set	CBZ-CR x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	401	412	388	397
Units: Days				
number (not applicable)				
25% Quartile	572	1217	576	1217

## Statistical analyses

<b>Statistical analysis title</b>	Log-Rank Test for treatment failure time PP
Comparison groups	ESL x Per Protocol Set v CBZ-CR x Per Protocol Set
Number of subjects included in analysis	785
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0005 <sup>[8]</sup>
Method	Logrank

Notes:

[8] - p-value (Log-Rank Test) - stratified by region: 0.0003

<b>Statistical analysis title</b>	Log-Rank Test for treatment failure time FAS
Comparison groups	ESL x Full Analysis Set v CBZ-CR x Full Analysis Set
Number of subjects included in analysis	813
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0004 <sup>[9]</sup>
Method	Logrank

Notes:

[9] - p-value (Log-Rank Test) - stratified by region: 0.0003

## Secondary: Treatment retention time

End point title	Treatment retention time
End point description: The time of the first occurrence of one of the following: Withdrawal of IMP due to AEs. Withdrawal of IMP due to lack of efficacy.	
End point type	Secondary
End point timeframe: From the first dose of IMP till the last IMP intake of the target dose + 1day	

End point values	ESL x Full Analysis Set	CBZ-CR x Full Analysis Set	ESL x Per Protocol Set	CBZ-CR x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	401	412	388	397
Units: Days				
number (confidence interval)				
25% Quartile	398 (293 to 546)	477 (384 to 723)	420 (298 to 563)	517 (392 to 790)

## Statistical analyses

<b>Statistical analysis title</b>	Log-Rank Test for treatment retention time PP
Comparison groups	ESL x Per Protocol Set v CBZ-CR x Per Protocol Set
Number of subjects included in analysis	785
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1299 <sup>[10]</sup>
Method	Logrank

Notes:

[10] - p-value (Log-Rank Test) - stratified by region: 0.1151

<b>Statistical analysis title</b>	Log-Rank Test for retention failure time FAS
Comparison groups	ESL x Full Analysis Set v CBZ-CR x Full Analysis Set
Number of subjects included in analysis	813
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1438 <sup>[11]</sup>
Method	Logrank

Notes:

[11] - p-value (Log-Rank Test) - stratified by region: 0.1249

## Secondary: Dose-response relationship

End point title	Dose-response relationship
End point description: The seizure frequency adjusted for the exposure time until end of evaluation, maintenance, and extension period	
End point type	Secondary
End point timeframe: Evaluation, Maintenance and Extension periods	

End point values	ESL 800 mg QD x Full Analysis Set	ESL 1200 mg QD x Full Analysis Set	ESL 1600 mg QD x Full Analysis Set	CBZ-CR 200 mg BID x Full Analysis Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	271	70	60	317
Units: Subjects				
number (not applicable)				
Evaluation Period	8	8	26	5
Maintenance Period	12	5	7	9
Extension Phase	28	10	3	26

End point values	CBZ-CR 400 mg BID x Full Analysis Set	CBZ-CR 600 mg BID x Full Analysis Set	ESL 800 mg QD x Per Protocol Set	ESL 1200 mg QD x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	61	34	262	69
Units: Subjects				
number (not applicable)				
Evaluation Period	4	12	8	8
Maintenance Period	6	3	11	5
Extension Phase	4	2	26	10

End point values	ESL 1600 mg QD x Per Protocol Set	CBZ-CR 200 mg BID x Per Protocol Set	CBZ-CR 400 mg BID x Per Protocol Set	CBZ-CR 600 mg BID x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	57	304	60	33
Units: Subjects				
number (not applicable)				
Evaluation Period	25	4	3	12
Maintenance Period	6	8	5	3
Extension Phase	3	26	3	2

### Statistical analyses

No statistical analyses for this end point

### Secondary: Seizure occurrence

End point title	Seizure occurrence
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End point description:

Number of subjects with at least 1 seizure during the respective phase / period of the last evaluated dose.

End point type	Secondary
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End point timeframe:

From Titration period till Extension phase

End point values	ESL x Full Analysis Set	CBZ-CR x Full Analysis Set	ESL x Per Protocol Set	CBZ-CR x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	401	412	388	397
Units: Subjects				
number (not applicable)				
Main Treatment Phase	104	74	100	71

Titration Period	35	36	34	36
Stabilization Period	21	21	21	21
Evaluation Period	42	21	41	19
Maintenance Period	24	16	22	15
Extension Phase	39	31	37	30

## Statistical analyses

No statistical analyses for this end point

## Secondary: Quality of life

End point title Quality of life

End point description:

The scores of the QOLIE-31

End point type Secondary

End point timeframe:

From Visit A1 (start of double-blind period) till the last Extension Phase Visit

End point values	ESL x Full Analysis Set	CBZ-CR x Full Analysis Set	ESL x Per Protocol Set	CBZ-CR x Per Protocol Set
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	401	412	388	397
Units: Scale				
arithmetic mean (standard deviation)				
Final score: Screening	64.5 (± 15.26)	63.9 (± 15.42)	64.6 (± 15.18)	63.9 (± 15.56)
Final score: Baseline	65.4 (± 15.03)	66 (± 15.63)	65.7 (± 14.94)	65.9 (± 15.69)
Final score: Visit 4	72 (± 14.27)	71.6 (± 14.78)	72.3 (± 14.1)	71.7 (± 14.82)
Final score: MPV2	72.8 (± 14.21)	74.5 (± 14.62)	72.8 (± 14.09)	74.5 (± 14.71)
Final score: FEV	72.7 (± 13.9)	75.5 (± 14.23)	72.8 (± 13.93)	75.5 (± 14.23)
Final score: EDV	66.1 (± 17.42)	66.3 (± 18.48)	66.2 (± 17.61)	66.2 (± 18.58)
T-score: Screening	51 (± 9.36)	50.6 (± 9.45)	51.1 (± 9.31)	50.7 (± 9.54)
T-score: Baseline	51.6 (± 9.22)	51.9 (± 9.59)	51.7 (± 9.16)	51.8 (± 9.62)
T-score: Visit 4	55.6 (± 8.75)	55.3 (± 9.06)	55.8 (± 8.64)	55.4 (± 9.09)
T-score: MPV2	56.1 (± 8.71)	57.1 (± 8.96)	56.1 (± 8.64)	57.1 (± 9.02)
T-score: FEV	56 (± 8.52)	57.8 (± 8.73)	56.1 (± 8.54)	57.8 (± 8.73)
T-score: EDV	52 (± 10.68)	52.1 (± 11.33)	52.1 (± 10.8)	52 (± 11.39)

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From the date of first study treatment up to 28 days after the last intake of the last evaluated dose of study medication.

Adverse event reporting additional description:

Each AE has to be documented with reference to intensity, date of occurrence, duration, frequency, treatment, and outcome. Furthermore, each AE has to be classified as serious or non-serious. Additionally, the investigator has to assess whether the AE is drug related or not. Changes of AEs and dates of ending have to be documented.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	15.1
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### Reporting groups

Reporting group title	ESL x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment.

Reporting group title	CBZ-CR x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment.

Reporting group title	ESL 800 mg QD x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment and the last evaluated dose was 800 mg QD of Eslicarbazepine Acetate.

Reporting group title	ESL 1200 mg QD x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment and the last evaluated dose was 1200 mg QD of Eslicarbazepine Acetate.

Reporting group title	ESL 1600 mg QD x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment and the last evaluated dose was 1600 mg QD of Eslicarbazepine Acetate.

Reporting group title	CBZ-CR 200 mg BID x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment and the last evaluated dose was 200 mg BID of Carbamazepine controlled-release.

Reporting group title	CBZ-CR 400 mg BID x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment and the last evaluated dose was 400 mg BID of Carbamazepine controlled-release.

Reporting group title	CBZ-CR 600 mg BID x Safety Set
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Reporting group description:

All patients who received at least one dose of study treatment and the last evaluated dose was 600 mg BID of Carbamazepine controlled-release.



<b>Serious adverse events</b>	ESL x Safety Set	CBZ-CR x Safety Set	ESL 800 mg QD x Safety Set
Total subjects affected by serious adverse events			
subjects affected / exposed	46 / 401 (11.47%)	50 / 412 (12.14%)	24 / 271 (8.86%)
number of deaths (all causes)	2	2	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Cholesteatoma			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Glioblastoma multiforme			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Glioma			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Lung adenocarcinoma			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Malignant melanoma			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Prostate cancer			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rectosigmoid cancer			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Hypertensive crisis			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Pregnancy, puerperium and perinatal conditions			
Abortion late			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Abortion spontaneous			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
High risk pregnancy			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
General disorders and administration site conditions			
Chest pain			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Infusion site inflammation			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Reproductive system and breast disorders			
Metrorrhagia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Respiratory, thoracic and mediastinal disorders			
Hydrothorax			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Completed suicide			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Depressive symptom			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychogenic seizure			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Suicide attempt			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Hepatic enzyme abnormal			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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

Alcohol poisoning			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Clavicle fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Contusion			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Craniocerebral injury			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dislocation of vertebra			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Fall			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Femur fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Foot fracture			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (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
Meniscus lesion			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Multiple fractures			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Patella fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Procedural vomiting			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Spinal column injury			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Spinal compression fracture			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Adams-stokes syndrome			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Aortic valve stenosis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (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
Atrial flutter			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Myocardial infarction			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Sick sinus syndrome			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral circulatory failure			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Cerebral ischaemia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	3 / 401 (0.75%)	4 / 412 (0.97%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			



subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	0 / 271 (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
Epileptic psychosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Grand mal convulsion			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Monoparesis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Partial seizures			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (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
Partial seizures with secondary generalisation			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	3 / 401 (0.75%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Colitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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

Inguinal hernia			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (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
Pancreatitis acute			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Pancreatitis necrotising			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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
Dermatitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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

Dermatitis allergic			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash generalised			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus ureteric			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (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

Bone pain			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Bursitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compartment syndrome			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (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
Endocarditis bacterial			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Respiratory tract infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	ESL 1200 mg QD x Safety Set	ESL 1600 mg QD x Safety Set	CBZ-CR 200 mg BID x Safety Set
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 70 (12.86%)	13 / 60 (21.67%)	45 / 317 (14.20%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Cholesteatoma			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma multiforme			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant melanoma			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Prostate cancer			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid cancer			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion late			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Abortion spontaneous			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
High risk pregnancy			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Infusion site inflammation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Non-cardiac chest pain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (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



Reproductive system and breast disorders			
Metrorrhagia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
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			
Hydrothorax			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Pulmonary embolism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Depressive symptom			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychogenic seizure			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			

subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Ankle fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Contusion			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Craniocerebral injury			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dislocation of vertebra			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Femur fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus lesion			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (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
Multiple fractures			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural vomiting			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column injury			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			
Adams-stokes syndrome			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Aortic valve stenosis			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Syncope			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral circulatory failure			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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 haemorrhage			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (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			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	1 / 70 (1.43%)	2 / 60 (3.33%)	3 / 317 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 70 (0.00%)	2 / 60 (3.33%)	0 / 317 (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
Epileptic psychosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand mal convulsion			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Ischaemic stroke			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoparesis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (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
Partial seizures			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures with secondary generalisation			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (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
Colitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Inguinal hernia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis necrotising			



subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatobiliary disorders</b>			
Cholecystitis acute			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin and subcutaneous tissue disorders</b>			
Angioedema			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Dermatitis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (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
Dermatitis allergic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash generalised			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal and urinary disorders</b>			

Calculus ureteric			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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 colic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			
Arthralgia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Back pain			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (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
Bone pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Compartment syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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 osteoarthritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			
Appendicitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis bacterial			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
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 tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (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
Tuberculosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	CBZ-CR 400 mg BID x Safety Set	CBZ-CR 600 mg BID x Safety Set	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 61 (6.56%)	1 / 34 (2.94%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholesteatoma			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma multiforme			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioma			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion late			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Abortion spontaneous			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
High risk pregnancy			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion site inflammation			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Metrorrhagia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Hydrothorax			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressive symptom			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic seizure			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hepatic enzyme increased subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dislocation of vertebra subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	



Fall			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus lesion			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural vomiting			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column injury			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Adams-stokes syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sick sinus syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral circulatory failure			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complex partial seizures			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epileptic psychosis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Grand mal convulsion			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoparesis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Simple partial seizures			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Diverticulitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

Angioedema			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash generalised			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Calculus ureteric			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis bacterial			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	



Gastroenteritis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
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>	ESL x Safety Set	CBZ-CR x Safety Set	ESL 800 mg QD x Safety Set
Total subjects affected by non-serious adverse events			
subjects affected / exposed	318 / 401 (79.30%)	342 / 412 (83.01%)	212 / 271 (78.23%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Haemangioma			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Haemangioma of liver			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Lipoma			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Lung neoplasm			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Melanocytic naevus			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	3	0	3
Osteoma			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Ovarian granulosa-theca cell tumour			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Skin papilloma			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Uterine leiomyoma			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	2	2	1
Vascular disorders			

Aortic arteriosclerosis subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	2 / 412 (0.49%) 2	0 / 271 (0.00%) 0
Aortic disorder subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Blood pressure fluctuation subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Flushing subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Haematoma subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	2 / 412 (0.49%) 3	0 / 271 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	3 / 412 (0.73%) 3	0 / 271 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	25 / 401 (6.23%) 27	28 / 412 (6.80%) 31	17 / 271 (6.27%) 19
Hypertensive angiopathy subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Hypertensive crisis subjects affected / exposed occurrences (all)	3 / 401 (0.75%) 3	3 / 412 (0.73%) 4	2 / 271 (0.74%) 2
Hypotension subjects affected / exposed occurrences (all)	6 / 401 (1.50%) 7	3 / 412 (0.73%) 3	5 / 271 (1.85%) 6
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 3	0 / 271 (0.00%) 0
Pregnancy, puerperium and perinatal conditions			

Abortion spontaneous subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Gestational diabetes subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Vomiting in pregnancy subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
General disorders and administration site conditions			
Application site erythema subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Asthenia subjects affected / exposed occurrences (all)	16 / 401 (3.99%) 19	16 / 412 (3.88%) 17	8 / 271 (2.95%) 11
Axillary pain subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	6 / 401 (1.50%) 9	8 / 412 (1.94%) 11	3 / 271 (1.11%) 3
Chills subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	3 / 412 (0.73%) 3	0 / 271 (0.00%) 0
Crying subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	2 / 412 (0.49%) 3	0 / 271 (0.00%) 0
Energy increased subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	37 / 401 (9.23%) 47	38 / 412 (9.22%) 52	22 / 271 (8.12%) 30
Feeling abnormal			

subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Feeling cold			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Feeling hot			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1
Gait disturbance			
subjects affected / exposed	3 / 401 (0.75%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	3	6	2
Generalised oedema			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hangover			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hyperthermia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	5	0
Inflammation			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Influenza like illness			
subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	1	6	0
Irritability			
subjects affected / exposed	7 / 401 (1.75%)	3 / 412 (0.73%)	3 / 271 (1.11%)
occurrences (all)	7	4	3
Localised oedema			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Malaise			
subjects affected / exposed	7 / 401 (1.75%)	5 / 412 (1.21%)	3 / 271 (1.11%)
occurrences (all)	10	6	3
Mucosal dryness			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Oedema peripheral			
subjects affected / exposed	4 / 401 (1.00%)	7 / 412 (1.70%)	4 / 271 (1.48%)
occurrences (all)	4	9	4
Pain			
subjects affected / exposed	2 / 401 (0.50%)	5 / 412 (1.21%)	1 / 271 (0.37%)
occurrences (all)	3	7	2
Pyrexia			
subjects affected / exposed	8 / 401 (2.00%)	12 / 412 (2.91%)	4 / 271 (1.48%)
occurrences (all)	10	14	5
Spinal pain			
subjects affected / exposed	2 / 401 (0.50%)	3 / 412 (0.73%)	1 / 271 (0.37%)
occurrences (all)	2	4	1
Thirst			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Drug hypersensitivity			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hypersensitivity			
subjects affected / exposed	2 / 401 (0.50%)	8 / 412 (1.94%)	1 / 271 (0.37%)
occurrences (all)	2	9	1
Multiple allergies			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Seasonal allergy			
subjects affected / exposed	3 / 401 (0.75%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	4	2	2
Social circumstances			
Menopause			

subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Breast pain			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cervical dysplasia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	1 / 401 (0.25%)	4 / 412 (0.97%)	1 / 271 (0.37%)
occurrences (all)	1	5	1
Endometrial hyperplasia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Erectile dysfunction			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	2	1	1
Fibrocystic breast disease			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Genital haemorrhage			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Menorrhagia			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Menstruation irregular			

subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	2 / 271 (0.74%)
occurrences (all)	2	3	2
Metrorrhagia			
subjects affected / exposed	5 / 401 (1.25%)	1 / 412 (0.24%)	3 / 271 (1.11%)
occurrences (all)	5	1	3
Oligomenorrhoea			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Ovarian cyst			
subjects affected / exposed	4 / 401 (1.00%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	4	3	2
Prostatitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Prostatomegaly			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Pruritus genital			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Rectocele			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Scrotal cyst			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Scrotal swelling			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Sexual dysfunction			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Spermatocele			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Testicular cyst			



subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Testicular microlithiasis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Uterine polyp			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Vaginal discharge			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Varicocele			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Asthma			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	2 / 271 (0.74%)
occurrences (all)	2	2	2
Atelectasis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Bronchospasm			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Cough			

subjects affected / exposed	10 / 401 (2.49%)	11 / 412 (2.67%)	8 / 271 (2.95%)
occurrences (all)	12	11	9
Dysphonia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	6 / 401 (1.50%)	3 / 412 (0.73%)	3 / 271 (1.11%)
occurrences (all)	8	3	4
Epistaxis			
subjects affected / exposed	5 / 401 (1.25%)	6 / 412 (1.46%)	4 / 271 (1.48%)
occurrences (all)	10	11	8
Hiccups			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hyperventilation			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Lung disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Nasal congestion			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Nasal oedema			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Nasal septum deviation			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Oropharyngeal pain			
subjects affected / exposed	6 / 401 (1.50%)	7 / 412 (1.70%)	4 / 271 (1.48%)
occurrences (all)	10	11	7
Pleurisy			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Pneumonia aspiration			

subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Pulmonary fibrosis subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	0 / 412 (0.00%) 0	2 / 271 (0.74%) 2
Pulmonary vascular disorder subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Reversible airways obstruction subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Rhinitis allergic subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 4	3 / 412 (0.73%) 3	2 / 271 (0.74%) 4
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	5 / 412 (1.21%) 5	1 / 271 (0.37%) 1
Stridor subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Vasomotor rhinitis subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Psychiatric disorders			
Acute stress disorder subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Adjustment disorder subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Affect lability subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	2 / 412 (0.49%) 2	0 / 271 (0.00%) 0
Affective disorder subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1

Aggression			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Agitation			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Alcohol abuse			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	20 / 401 (4.99%)	19 / 412 (4.61%)	8 / 271 (2.95%)
occurrences (all)	24	23	10
Anxiety disorder			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Apathy			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Bradyphrenia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Bulimia nervosa			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Claustrophobia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	4 / 401 (1.00%)	7 / 412 (1.70%)	3 / 271 (1.11%)
occurrences (all)	4	9	3
Deja vu			

subjects affected / exposed	3 / 401 (0.75%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	6	1	5
Delirium			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	7 / 401 (1.75%)	6 / 412 (1.46%)	3 / 271 (1.11%)
occurrences (all)	9	6	4
Depression			
subjects affected / exposed	7 / 401 (1.75%)	8 / 412 (1.94%)	2 / 271 (0.74%)
occurrences (all)	7	11	2
Disorientation			
subjects affected / exposed	3 / 401 (0.75%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	3	6	2
Drug abuse			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Dysphemia			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	2	0	0
Dysphoria			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Emotional disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hallucination, auditory			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hypervigilance			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1
Impaired reasoning			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			

subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	4	1
Insomnia			
subjects affected / exposed	14 / 401 (3.49%)	12 / 412 (2.91%)	8 / 271 (2.95%)
occurrences (all)	15	13	9
Libido decreased			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Mental disorder			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Mood altered			
subjects affected / exposed	3 / 401 (0.75%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	3	1	1
Mood disorder due to a general medical condition			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Mood swings			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Nervousness			
subjects affected / exposed	7 / 401 (1.75%)	10 / 412 (2.43%)	6 / 271 (2.21%)
occurrences (all)	8	11	7
Nightmare			
subjects affected / exposed	3 / 401 (0.75%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	3	0	1
Panic attack			
subjects affected / exposed	1 / 401 (0.25%)	4 / 412 (0.97%)	0 / 271 (0.00%)
occurrences (all)	1	5	0
Panic disorder			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Personality change			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0

Personality disorder			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Psychogenic seizure			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Psychotic disorder			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	2	3	1
Sleep disorder			
subjects affected / exposed	4 / 401 (1.00%)	4 / 412 (0.97%)	3 / 271 (1.11%)
occurrences (all)	5	4	3
Sleep talking			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Social avoidant behaviour			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Staring			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Stress			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Suicidal ideation			
subjects affected / exposed	3 / 401 (0.75%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	3	2	1
Tachyphrenia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Tension			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0

Tic			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Biliary dyskinesia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	2	1	0
Cholangitis acute			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cholecystitis chronic			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cholelithiasis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Drug-induced liver injury			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Hepatic pain			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hepatic steatosis			
subjects affected / exposed	4 / 401 (1.00%)	5 / 412 (1.21%)	3 / 271 (1.11%)
occurrences (all)	4	5	3
Hepatitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hepatitis acute			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hepatomegaly			



subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hepatotoxicity			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2
Liver disorder			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	4 / 401 (1.00%)	3 / 412 (0.73%)	4 / 271 (1.48%)
occurrences (all)	4	3	4
Alanine aminotransferase increased			
subjects affected / exposed	9 / 401 (2.24%)	10 / 412 (2.43%)	5 / 271 (1.85%)
occurrences (all)	9	11	5
Anti-gad antibody positive			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Anti-islet cell antibody positive			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 401 (1.50%)	9 / 412 (2.18%)	2 / 271 (0.74%)
occurrences (all)	6	9	2
Biopsy endometrium			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Blood 25-hydroxycholecalciferol decreased			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase decreased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 401 (0.25%)	5 / 412 (1.21%)	1 / 271 (0.37%)
occurrences (all)	3	9	3
Blood bilirubin increased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Blood calcium decreased			
subjects affected / exposed	0 / 401 (0.00%)	4 / 412 (0.97%)	0 / 271 (0.00%)
occurrences (all)	0	5	0
Blood calcium increased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Blood chloride decreased			
subjects affected / exposed	5 / 401 (1.25%)	1 / 412 (0.24%)	5 / 271 (1.85%)
occurrences (all)	5	1	5
Blood cholesterol increased			
subjects affected / exposed	1 / 401 (0.25%)	6 / 412 (1.46%)	1 / 271 (0.37%)
occurrences (all)	1	6	1
Blood creatine phosphokinase increased			
subjects affected / exposed	19 / 401 (4.74%)	19 / 412 (4.61%)	12 / 271 (4.43%)
occurrences (all)	22	20	14
Blood creatinine decreased			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Blood folate decreased			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Blood glucose decreased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Blood glucose increased			
subjects affected / exposed	4 / 401 (1.00%)	3 / 412 (0.73%)	4 / 271 (1.48%)
occurrences (all)	4	3	4
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	7 / 401 (1.75%)	2 / 412 (0.49%)	5 / 271 (1.85%)
occurrences (all)	13	2	11
Blood parathyroid hormone decreased			
subjects affected / exposed	4 / 401 (1.00%)	1 / 412 (0.24%)	4 / 271 (1.48%)
occurrences (all)	4	1	4
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	4	0
Blood phosphorus increased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Blood potassium decreased			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Blood potassium increased			
subjects affected / exposed	3 / 401 (0.75%)	2 / 412 (0.49%)	2 / 271 (0.74%)
occurrences (all)	3	2	2
Blood pressure decreased			
subjects affected / exposed	3 / 401 (0.75%)	1 / 412 (0.24%)	3 / 271 (1.11%)
occurrences (all)	3	1	3
Blood pressure increased			

subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	3	1
Blood sodium decreased			
subjects affected / exposed	5 / 401 (1.25%)	2 / 412 (0.49%)	4 / 271 (1.48%)
occurrences (all)	5	2	4
Blood sodium increased			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	1 / 271 (0.37%)
occurrences (all)	1	3	1
Blood triglycerides			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Blood triglycerides increased			
subjects affected / exposed	5 / 401 (1.25%)	7 / 412 (1.70%)	3 / 271 (1.11%)
occurrences (all)	8	16	6
Blood urea increased			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Blood urine present			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	2	1	1
Body mass index decreased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Body mass index increased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	3	1	3
Body temperature increased			

subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	2	2	2
Bone density increased			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	2 / 271 (0.74%)
occurrences (all)	2	2	2
C-reactive protein increased			
subjects affected / exposed	16 / 401 (3.99%)	20 / 412 (4.85%)	11 / 271 (4.06%)
occurrences (all)	20	26	14
Coagulation test abnormal			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2
Coagulation time prolonged			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Colonoscopy			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Electrocardiogram abnormal			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram qrs complex prolonged			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram qt prolonged			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Eosinophil count decreased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Eosinophil count increased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	2	2	2
Gamma-glutamyltransferase abnormal			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	21 / 401 (5.24%)	65 / 412 (15.78%)	13 / 271 (4.80%)
occurrences (all)	26	76	14
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Haematocrit decreased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Haemoglobin decreased			
subjects affected / exposed	4 / 401 (1.00%)	4 / 412 (0.97%)	3 / 271 (1.11%)
occurrences (all)	8	6	6
Heart rate decreased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Hepatic enzyme increased			
subjects affected / exposed	4 / 401 (1.00%)	4 / 412 (0.97%)	3 / 271 (1.11%)
occurrences (all)	5	4	4
High density lipoprotein decreased			
subjects affected / exposed	1 / 401 (0.25%)	4 / 412 (0.97%)	1 / 271 (0.37%)
occurrences (all)	1	5	1
International normalised ratio decreased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	6 / 401 (1.50%)	6 / 412 (1.46%)	6 / 271 (2.21%)
occurrences (all)	6	7	6
Intraocular pressure increased			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Liver function test abnormal			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Low density lipoprotein increased			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	2	2	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Monocyte count decreased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
N-telopeptide			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
N-telopeptide urine increased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Neutrophil count increased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Osteocalcin decreased			
subjects affected / exposed	4 / 401 (1.00%)	2 / 412 (0.49%)	4 / 271 (1.48%)
occurrences (all)	4	2	4
Osteocalcin increased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Positive rombergism			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Protein total decreased			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Protein total increased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Red blood cell count decreased			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Serum ferritin increased			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Tandem gait test abnormal			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Thyroid function test abnormal			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Thyroxine decreased			
subjects affected / exposed	4 / 401 (1.00%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	4	1	2
Thyroxine free decreased			
subjects affected / exposed	7 / 401 (1.75%)	5 / 412 (1.21%)	4 / 271 (1.48%)
occurrences (all)	7	6	4
Transaminases increased			
subjects affected / exposed	3 / 401 (0.75%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	3	3	2
Tri-iodothyronine free increased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Tri-iodothyronine increased			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Urine analysis abnormal			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Vitamin d decreased			



subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	1 / 271 (0.37%)
occurrences (all)	1	3	1
Weight decreased			
subjects affected / exposed	4 / 401 (1.00%)	6 / 412 (1.46%)	3 / 271 (1.11%)
occurrences (all)	4	6	3
Weight increased			
subjects affected / exposed	13 / 401 (3.24%)	19 / 412 (4.61%)	10 / 271 (3.69%)
occurrences (all)	13	19	10
White blood cell count decreased			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
White blood cells urine positive			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Animal bite			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1
Ankle fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Arthropod sting			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Brain contusion			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Clavicle fracture			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Concussion			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Contusion			
subjects affected / exposed	8 / 401 (2.00%)	5 / 412 (1.21%)	5 / 271 (1.85%)
occurrences (all)	10	5	7
Craniocerebral injury			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Ear injury			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Excoriation			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	2	2	0
Expired drug administered			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Face injury			
subjects affected / exposed	3 / 401 (0.75%)	2 / 412 (0.49%)	2 / 271 (0.74%)
occurrences (all)	3	2	2
Facial bones fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	5 / 401 (1.25%)	12 / 412 (2.91%)	3 / 271 (1.11%)
occurrences (all)	7	20	5
Foot fracture			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2
Hand fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Head injury			

subjects affected / exposed	3 / 401 (0.75%)	2 / 412 (0.49%)	2 / 271 (0.74%)
occurrences (all)	3	2	2
Injury			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Joint dislocation			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Joint injury			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Laceration			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Ligament rupture			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Ligament sprain			
subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	1 / 271 (0.37%)
occurrences (all)	1	3	1
Limb injury			
subjects affected / exposed	5 / 401 (1.25%)	5 / 412 (1.21%)	3 / 271 (1.11%)
occurrences (all)	5	5	3
Lip injury			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Muscle rupture			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Muscle strain			
subjects affected / exposed	4 / 401 (1.00%)	0 / 412 (0.00%)	3 / 271 (1.11%)
occurrences (all)	7	0	3
Nail injury			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Overdose			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 401 (0.00%)	5 / 412 (1.21%)	0 / 271 (0.00%)
occurrences (all)	0	6	0
Scratch			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Skeletal injury			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Soft tissue injury			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Thermal burn			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Wound			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Wrist fracture			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Bruton's agammaglobulinaemia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Congenital cerebrovascular anomaly			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Cortical dysplasia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Gilbert's syndrome			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hydrocele			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	3 / 401 (0.75%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	3	3	2
Aortic valve incompetence			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Arrhythmia			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Atrial fibrillation			
subjects affected / exposed	3 / 401 (0.75%)	2 / 412 (0.49%)	3 / 271 (1.11%)
occurrences (all)	4	3	4
Atrial flutter			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block first degree			
subjects affected / exposed	1 / 401 (0.25%)	5 / 412 (1.21%)	1 / 271 (0.37%)
occurrences (all)	1	5	1
Atrioventricular block second degree			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1

Bradycardia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Bundle branch block left			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Bundle branch block right			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	2	1	1
Cardiac disorder			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cardiac failure			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Cardiac failure chronic			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cardiomyopathy			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cardiovascular disorder			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	2	2	1
Hypertensive heart disease			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Left atrial dilatation			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Left ventricular hypertrophy			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1
Mitral valve incompetence			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2

Mitral valve prolapse subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	1 / 412 (0.24%) 1	1 / 271 (0.37%) 1
Myocardial ischaemia subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	4 / 401 (1.00%) 6	5 / 412 (1.21%) 5	3 / 271 (1.11%) 4
Sinus bradycardia subjects affected / exposed occurrences (all)	3 / 401 (0.75%) 3	3 / 412 (0.73%) 3	2 / 271 (0.74%) 2
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Supraventricular extrasystoles subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Tachycardia subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	5 / 412 (1.21%) 5	1 / 271 (0.37%) 1
Tachycardia paroxysmal subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Ventricular extrasystoles subjects affected / exposed occurrences (all)	3 / 401 (0.75%) 3	0 / 412 (0.00%) 0	3 / 271 (1.11%) 3
Nervous system disorders			
Action tremor subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Altered state of consciousness subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Amnesia			

subjects affected / exposed	4 / 401 (1.00%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	4	1	1
Aphasia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Arachnoid cyst			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Areflexia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Ataxia			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Balance disorder			
subjects affected / exposed	2 / 401 (0.50%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	2	6	2
Burning sensation			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Carotid artery stenosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Cerebrovascular accident			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Cerebrovascular disorder			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0



Cervicobrachial syndrome subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	3 / 412 (0.73%) 4	0 / 271 (0.00%) 0
Cognitive disorder subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	4 / 412 (0.97%) 4	2 / 271 (0.74%) 2
Complex partial seizures subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 3	2 / 412 (0.49%) 2	1 / 271 (0.37%) 3
Convulsion subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	1 / 412 (0.24%) 1	1 / 271 (0.37%) 1
Coordination abnormal subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	3 / 412 (0.73%) 3	0 / 271 (0.00%) 0
Dementia alzheimer's type subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Disturbance in attention subjects affected / exposed occurrences (all)	11 / 401 (2.74%) 12	6 / 412 (1.46%) 6	8 / 271 (2.95%) 8
Dizziness subjects affected / exposed occurrences (all)	79 / 401 (19.70%) 146	65 / 412 (15.78%) 120	43 / 271 (15.87%) 85
Dysarthria subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	3 / 401 (0.75%) 4	0 / 412 (0.00%) 0	3 / 271 (1.11%) 4
Dystonia subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Epilepsy subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	2 / 412 (0.49%) 2	1 / 271 (0.37%) 1

Epileptic aura			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Grand mal convulsion			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	2	1	0
Head discomfort			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	119 / 401 (29.68%)	116 / 412 (28.16%)	75 / 271 (27.68%)
occurrences (all)	254	262	159
Hemiparesis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hippocampal sclerosis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Hyperreflexia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	2
Hypersomnia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hypoaesthesia			
subjects affected / exposed	3 / 401 (0.75%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	3	3	2
Idiopathic generalised epilepsy			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Incoherent			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2

Loss of consciousness			
subjects affected / exposed	1 / 401 (0.25%)	4 / 412 (0.97%)	1 / 271 (0.37%)
occurrences (all)	1	4	1
Lumbar radiculopathy			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Lumbosacral plexus lesion			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	10 / 401 (2.49%)	12 / 412 (2.91%)	4 / 271 (1.48%)
occurrences (all)	10	13	4
Mental impairment			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	6 / 401 (1.50%)	7 / 412 (1.70%)	5 / 271 (1.85%)
occurrences (all)	11	16	10
Monoparesis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Muscle spasticity			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Myoclonus			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Neurotoxicity			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Nystagmus			
subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	1 / 271 (0.37%)
occurrences (all)	1	4	1
Paraesthesia			
subjects affected / exposed	6 / 401 (1.50%)	11 / 412 (2.67%)	4 / 271 (1.48%)
occurrences (all)	7	34	4

Parosmia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Partial seizures with secondary generalisation			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	2	2	1
Peripheral nerve paresis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Poor quality sleep			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Postictal headache			
subjects affected / exposed	3 / 401 (0.75%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	4	1	0
Postictal paralysis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Postictal state			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Presyncope			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	3	2	2
Psychomotor hyperactivity			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Reflexes abnormal			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	3	0
Sedation			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Sensory disturbance			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Simple partial seizures			
subjects affected / exposed	1 / 401 (0.25%)	4 / 412 (0.97%)	0 / 271 (0.00%)
occurrences (all)	1	5	0
Slow speech			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Somnolence			
subjects affected / exposed	34 / 401 (8.48%)	43 / 412 (10.44%)	16 / 271 (5.90%)
occurrences (all)	52	57	22
Syncope			
subjects affected / exposed	6 / 401 (1.50%)	14 / 412 (3.40%)	3 / 271 (1.11%)
occurrences (all)	13	17	3
Tension headache			
subjects affected / exposed	2 / 401 (0.50%)	5 / 412 (1.21%)	0 / 271 (0.00%)
occurrences (all)	5	7	0
Tongue biting			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Transient ischaemic attack			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Tremor			
subjects affected / exposed	10 / 401 (2.49%)	6 / 412 (1.46%)	5 / 271 (1.85%)
occurrences (all)	26	6	8
Vascular encephalopathy			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

Agranulocytosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Anaemia			
subjects affected / exposed	9 / 401 (2.24%)	11 / 412 (2.67%)	5 / 271 (1.85%)
occurrences (all)	11	11	6
Bicytopenia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Haemorrhagic anaemia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hypochromic anaemia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Leukocytosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	4 / 401 (1.00%)	6 / 412 (1.46%)	2 / 271 (0.74%)
occurrences (all)	4	8	2
Lymph node pain			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	3 / 401 (0.75%)	5 / 412 (1.21%)	2 / 271 (0.74%)
occurrences (all)	3	5	2
Lymphopenia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	2	0	0

Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Pancytopenia subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	5 / 412 (1.21%) 5	0 / 271 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Ear and labyrinth disorders			
Deafness subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Deafness neurosensory subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Ear congestion subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 3	2 / 412 (0.49%) 2	1 / 271 (0.37%) 1
Hearing impaired subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Hyperacusis subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Hypoacusis			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Mastoid disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Neurosensory hypoacusis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Sudden hearing loss			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	6 / 401 (1.50%)	6 / 412 (1.46%)	3 / 271 (1.11%)
occurrences (all)	6	6	3
Vertigo			
subjects affected / exposed	16 / 401 (3.99%)	26 / 412 (6.31%)	10 / 271 (3.69%)
occurrences (all)	25	46	16
Vertigo positional			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Vestibular ataxia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Vestibular disorder			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	4	0	3
Eye disorders			
Asthenopia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Astigmatism			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Blepharitis			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1



Blindness transient			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	3 / 401 (0.75%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	3	0	2
Conjunctivitis			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Diplopia			
subjects affected / exposed	2 / 401 (0.50%)	4 / 412 (0.97%)	1 / 271 (0.37%)
occurrences (all)	2	5	1
Dry eye			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Eczema eyelids			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Eye movement disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Eye oedema			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Eye pain			
subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	1	4	0
Eyelid oedema			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Eyelids pruritus			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0

Glaucoma			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Keratoconus			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Myopia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Pterygium			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	8 / 401 (2.00%)	11 / 412 (2.67%)	6 / 271 (2.21%)
occurrences (all)	8	12	6
Visual impairment			
subjects affected / exposed	3 / 401 (0.75%)	4 / 412 (0.97%)	1 / 271 (0.37%)
occurrences (all)	3	4	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Abdominal distension			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	2	0
Abdominal pain			
subjects affected / exposed	9 / 401 (2.24%)	13 / 412 (3.16%)	2 / 271 (0.74%)
occurrences (all)	15	16	8
Abdominal pain upper			
subjects affected / exposed	17 / 401 (4.24%)	21 / 412 (5.10%)	10 / 271 (3.69%)
occurrences (all)	45	24	11
Aphthous stomatitis			

subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Breath odour			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Coeliac disease			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Colitis ulcerative			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Colonic polyp			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Constipation			
subjects affected / exposed	4 / 401 (1.00%)	6 / 412 (1.46%)	2 / 271 (0.74%)
occurrences (all)	5	6	2
Dental caries			
subjects affected / exposed	2 / 401 (0.50%)	5 / 412 (1.21%)	1 / 271 (0.37%)
occurrences (all)	2	7	1
Diarrhoea			
subjects affected / exposed	20 / 401 (4.99%)	19 / 412 (4.61%)	14 / 271 (5.17%)
occurrences (all)	33	29	19
Diverticulum intestinal			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Dry mouth			
subjects affected / exposed	3 / 401 (0.75%)	9 / 412 (2.18%)	1 / 271 (0.37%)
occurrences (all)	3	11	1
Duodenal ulcer			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Duodenogastric reflux			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2
Dyspepsia			

subjects affected / exposed	7 / 401 (1.75%)	9 / 412 (2.18%)	7 / 271 (2.58%)
occurrences (all)	9	11	9
Enteritis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Enterocolitis			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Erosive duodenitis			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2
Eructation			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	2	2	2
Flatulence			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	3	0	1
Food poisoning			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Frequent bowel movements			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Gastric mucosa erythema			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Gastric ulcer			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	4 / 401 (1.00%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	4	3	1
Gastritis erosive			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2
Gastroduodenitis			

subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 401 (1.25%)	1 / 412 (0.24%)	4 / 271 (1.48%)
occurrences (all)	5	1	4
Haematochezia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Hiatus hernia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hypoaesthesia oral			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Intestinal haemorrhage			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	4	0
Irritable bowel syndrome			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1
Leukoplakia oral			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	2	1	0
Nausea			
subjects affected / exposed	41 / 401 (10.22%)	50 / 412 (12.14%)	18 / 271 (6.64%)
occurrences (all)	79	84	37
Odynophagia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Oesophagitis			

subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Oral mucosal blistering			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Pancreatic steatosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Pancreatitis chronic			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	3 / 401 (0.75%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	3	2	1
Periodontal disease			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Polyp colorectal			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Proctalgia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Rectal haemorrhage			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Reflux gastritis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Tongue ulceration			

subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Tooth loss			
subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Toothache			
subjects affected / exposed occurrences (all)	9 / 401 (2.24%) 9	11 / 412 (2.67%) 14	8 / 271 (2.95%) 8
Vomiting			
subjects affected / exposed occurrences (all)	20 / 401 (4.99%) 28	23 / 412 (5.58%) 39	10 / 271 (3.69%) 14
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed occurrences (all)	5 / 401 (1.25%) 5	3 / 412 (0.73%) 3	2 / 271 (0.74%) 2
Alopecia			
subjects affected / exposed occurrences (all)	3 / 401 (0.75%) 6	5 / 412 (1.21%) 5	2 / 271 (0.74%) 3
Blister			
subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Dermal cyst			
subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Dermatitis			
subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 2	5 / 412 (1.21%) 6	1 / 271 (0.37%) 2
Dermatitis acneiform			
subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Dermatitis allergic			
subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	9 / 412 (2.18%) 9	2 / 271 (0.74%) 2
Drug eruption			
subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0

Dry skin			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Eczema			
subjects affected / exposed	2 / 401 (0.50%)	5 / 412 (1.21%)	2 / 271 (0.74%)
occurrences (all)	2	5	2
Erythema			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	2	1	1
Hyperhidrosis			
subjects affected / exposed	3 / 401 (0.75%)	6 / 412 (1.46%)	2 / 271 (0.74%)
occurrences (all)	3	9	2
Night sweats			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Photosensitivity reaction			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Pigmentation disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	4 / 401 (1.00%)	4 / 412 (0.97%)	2 / 271 (0.74%)
occurrences (all)	4	4	2
Pruritus generalised			
subjects affected / exposed	1 / 401 (0.25%)	4 / 412 (0.97%)	0 / 271 (0.00%)
occurrences (all)	1	4	0
Psoriasis			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	17 / 401 (4.24%)	15 / 412 (3.64%)	9 / 271 (3.32%)
occurrences (all)	18	18	10
Rash generalised			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0



Rash maculo-papular subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Rash papular subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	2 / 412 (0.49%) 2	0 / 271 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	1 / 412 (0.24%) 1	1 / 271 (0.37%) 1
Scar subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Seborrhoea subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Seborrhoeic dermatitis subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	1 / 412 (0.24%) 1	1 / 271 (0.37%) 1
Skin depigmentation subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Skin exfoliation subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Skin irritation subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	1 / 412 (0.24%) 1	1 / 271 (0.37%) 1
Skin lesion subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	1 / 412 (0.24%) 1	1 / 271 (0.37%) 1
Skin reaction subjects affected / exposed occurrences (all)	3 / 401 (0.75%) 3	0 / 412 (0.00%) 0	3 / 271 (1.11%) 3
Skin striae subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0

Subcutaneous nodule			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Sweat gland disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Swelling face			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Toxic skin eruption			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Urticaria			
subjects affected / exposed	4 / 401 (1.00%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	4	0	2
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Dysuria			
subjects affected / exposed	3 / 401 (0.75%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	3	1	2
Haematuria			
subjects affected / exposed	4 / 401 (1.00%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	4	3	2
Leukocyturia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	3	4	0
Nocturia			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Pyuria			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Renal colic			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	2	2	1
Renal cyst			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Renal impairment			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Renal pain			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	3	1
Urethral pain			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Urinary hesitation			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Urinary tract disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Empty sella syndrome			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2

Hyperparathyroidism subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	0 / 271 (0.00%) 0
Hyperparathyroidism secondary subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	14 / 401 (3.49%) 15	11 / 412 (2.67%) 11	9 / 271 (3.32%) 10
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis subjects affected / exposed occurrences (all)	1 / 401 (0.25%) 1	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Arthralgia subjects affected / exposed occurrences (all)	7 / 401 (1.75%) 8	12 / 412 (2.91%) 17	3 / 271 (1.11%) 3
Arthritis subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	1 / 412 (0.24%) 3	2 / 271 (0.74%) 2
Arthropathy subjects affected / exposed occurrences (all)	0 / 401 (0.00%) 0	1 / 412 (0.24%) 1	0 / 271 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	26 / 401 (6.48%) 31	21 / 412 (5.10%) 23	15 / 271 (5.54%) 17
Bone pain subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	2 / 412 (0.49%) 2	2 / 271 (0.74%) 2
Bursitis subjects affected / exposed occurrences (all)	2 / 401 (0.50%) 2	0 / 412 (0.00%) 0	1 / 271 (0.37%) 1
Costochondritis			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Exostosis			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Flank pain			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Intervertebral disc protrusion			
subjects affected / exposed	3 / 401 (0.75%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	3	2	1
Joint crepitation			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Limb asymmetry			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	8 / 401 (2.00%)	6 / 412 (1.46%)	4 / 271 (1.48%)
occurrences (all)	10	6	4
Muscle tightness			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Muscle twitching			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Muscular weakness			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Musculoskeletal chest pain			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Musculoskeletal pain			
subjects affected / exposed	5 / 401 (1.25%)	6 / 412 (1.46%)	2 / 271 (0.74%)
occurrences (all)	5	7	2
Musculoskeletal stiffness			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	3 / 401 (0.75%)	6 / 412 (1.46%)	0 / 271 (0.00%)
occurrences (all)	4	10	0
Myokymia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	2	2	0
Myositis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	6 / 401 (1.50%)	9 / 412 (2.18%)	5 / 271 (1.85%)
occurrences (all)	6	9	5
Osteoarthritis			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	2 / 271 (0.74%)
occurrences (all)	2	2	2
Osteochondritis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Osteochondrosis			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Osteoporosis			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Pain in extremity			
subjects affected / exposed	6 / 401 (1.50%)	13 / 412 (3.16%)	6 / 271 (2.21%)
occurrences (all)	9	15	9
Periostitis			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Rheumatoid arthritis			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	2	0	1
Rotator cuff syndrome			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Sle arthritis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Soft tissue mass			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Spinal osteoarthritis			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	4	0	1
Spondylolisthesis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Sympathetic posterior cervical syndrome			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Temporomandibular joint syndrome			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Tendonitis			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Tenosynovitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abdominal abscess			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Acarodermatitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Acute sinusitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Acute tonsillitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Body tinea			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	8 / 401 (2.00%)	12 / 412 (2.91%)	6 / 271 (2.21%)
occurrences (all)	10	13	8
Bronchopneumonia			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Cellulitis			
subjects affected / exposed	3 / 401 (0.75%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	3	0	2
Cervicitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	5 / 401 (1.25%)	5 / 412 (1.21%)	5 / 271 (1.85%)
occurrences (all)	5	6	5
Diverticulitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	4 / 401 (1.00%)	2 / 412 (0.49%)	4 / 271 (1.48%)
occurrences (all)	7	2	7
Enterovirus infection			



subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Erysipelas			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Eye infection viral			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Eyelid infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Folliculitis			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Fungal infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Gardnerella infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	5 / 401 (1.25%)	9 / 412 (2.18%)	4 / 271 (1.48%)
occurrences (all)	7	10	6
Gastroenteritis viral			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	1	3	0
Gastrointestinal infection			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal viral infection			

subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Genital abscess			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Gingival abscess			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Helicobacter infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Helminthic infection			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hepatitis c			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hepatitis viral			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Herpes dermatitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	20 / 401 (4.99%)	25 / 412 (6.07%)	15 / 271 (5.54%)
occurrences (all)	26	27	20
Laryngitis			

subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Lobar pneumonia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	37 / 401 (9.23%)	47 / 412 (11.41%)	22 / 271 (8.12%)
occurrences (all)	56	67	32
Oesophagitis bacterial			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Oral herpes			
subjects affected / exposed	2 / 401 (0.50%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	2	1	2
Oral infection			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Orchitis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	2	0
Parotitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	0 / 401 (0.00%)	2 / 412 (0.49%)	0 / 271 (0.00%)
occurrences (all)	0	3	0
Pharyngitis			

subjects affected / exposed	5 / 401 (1.25%)	6 / 412 (1.46%)	3 / 271 (1.11%)
occurrences (all)	6	12	4
Pharyngitis streptococcal			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	1 / 271 (0.37%)
occurrences (all)	1	1	1
Pneumonia			
subjects affected / exposed	2 / 401 (0.50%)	3 / 412 (0.73%)	2 / 271 (0.74%)
occurrences (all)	2	3	2
Proctitis chlamydial			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Pulpitis dental			
subjects affected / exposed	3 / 401 (0.75%)	4 / 412 (0.97%)	3 / 271 (1.11%)
occurrences (all)	3	5	3
Pyelonephritis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	9 / 401 (2.24%)	8 / 412 (1.94%)	6 / 271 (2.21%)
occurrences (all)	10	10	7
Respiratory tract infection viral			
subjects affected / exposed	6 / 401 (1.50%)	9 / 412 (2.18%)	3 / 271 (1.11%)
occurrences (all)	6	9	3
Rhinitis			
subjects affected / exposed	1 / 401 (0.25%)	3 / 412 (0.73%)	1 / 271 (0.37%)
occurrences (all)	1	3	1
Salmonellosis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Salpingo-oophoritis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	6 / 401 (1.50%)	8 / 412 (1.94%)	4 / 271 (1.48%)
occurrences (all)	6	9	4
Skin infection			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Staphylococcal infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Tinea cruris			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Tinea manuum			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Tinea versicolour			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Tonsillitis			
subjects affected / exposed	4 / 401 (1.00%)	7 / 412 (1.70%)	3 / 271 (1.11%)
occurrences (all)	4	11	3
Tonsillitis streptococcal			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Tooth abscess			
subjects affected / exposed	2 / 401 (0.50%)	5 / 412 (1.21%)	2 / 271 (0.74%)
occurrences (all)	2	5	2
Tooth infection			
subjects affected / exposed	1 / 401 (0.25%)	6 / 412 (1.46%)	1 / 271 (0.37%)
occurrences (all)	1	10	1
Tracheitis			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Tuberculosis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	10 / 401 (2.49%)	10 / 412 (2.43%)	7 / 271 (2.58%)
occurrences (all)	10	16	7
Urethritis			

subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	8 / 401 (2.00%)	13 / 412 (3.16%)	6 / 271 (2.21%)
occurrences (all)	8	13	6
Urinary tract infection bacterial			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	8 / 401 (2.00%)	9 / 412 (2.18%)	8 / 271 (2.95%)
occurrences (all)	11	13	11
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 401 (0.75%)	0 / 412 (0.00%)	3 / 271 (1.11%)
occurrences (all)	3	0	3
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	6 / 401 (1.50%)	1 / 412 (0.24%)	3 / 271 (1.11%)
occurrences (all)	6	1	3
Dehydration			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus			
subjects affected / exposed	3 / 401 (0.75%)	1 / 412 (0.24%)	2 / 271 (0.74%)
occurrences (all)	6	1	4
Dyslipidaemia			
subjects affected / exposed	3 / 401 (0.75%)	8 / 412 (1.94%)	2 / 271 (0.74%)
occurrences (all)	3	9	2

Folate deficiency			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Hypercholesterolaemia			
subjects affected / exposed	6 / 401 (1.50%)	6 / 412 (1.46%)	4 / 271 (1.48%)
occurrences (all)	7	6	5
Hyperglycaemia			
subjects affected / exposed	1 / 401 (0.25%)	4 / 412 (0.97%)	0 / 271 (0.00%)
occurrences (all)	2	5	0
Hyperinsulinism			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	2 / 401 (0.50%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	2	0	2
Hyperlipidaemia			
subjects affected / exposed	3 / 401 (0.75%)	3 / 412 (0.73%)	3 / 271 (1.11%)
occurrences (all)	3	3	3
Hyperphagia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	5 / 401 (1.25%)	4 / 412 (0.97%)	4 / 271 (1.48%)
occurrences (all)	5	5	4
Hypocalcaemia			
subjects affected / exposed	1 / 401 (0.25%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Hypochloraemia			
subjects affected / exposed	3 / 401 (0.75%)	0 / 412 (0.00%)	2 / 271 (0.74%)
occurrences (all)	3	0	2
Hypoglycaemia			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0

Hypokalaemia			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	13 / 401 (3.24%)	4 / 412 (0.97%)	4 / 271 (1.48%)
occurrences (all)	14	5	4
Increased appetite			
subjects affected / exposed	2 / 401 (0.50%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	2	3	0
Metabolic disorder			
subjects affected / exposed	1 / 401 (0.25%)	0 / 412 (0.00%)	1 / 271 (0.37%)
occurrences (all)	1	0	1
Obesity			
subjects affected / exposed	2 / 401 (0.50%)	6 / 412 (1.46%)	1 / 271 (0.37%)
occurrences (all)	2	6	1
Overweight			
subjects affected / exposed	2 / 401 (0.50%)	2 / 412 (0.49%)	1 / 271 (0.37%)
occurrences (all)	2	2	1
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 401 (0.00%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	0	1	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 401 (0.25%)	1 / 412 (0.24%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Vitamin d deficiency			
subjects affected / exposed	0 / 401 (0.00%)	3 / 412 (0.73%)	0 / 271 (0.00%)
occurrences (all)	0	3	0

<b>Non-serious adverse events</b>	ESL 1200 mg QD x Safety Set	ESL 1600 mg QD x Safety Set	CBZ-CR 200 mg BID x Safety Set
Total subjects affected by non-serious adverse events			
subjects affected / exposed	55 / 70 (78.57%)	51 / 60 (85.00%)	258 / 317 (81.39%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Haemangioma			



subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Haemangioma of liver			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Lipoma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Lung neoplasm			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Melanocytic naevus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Osteoma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Ovarian granulosa-theca cell tumour			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Skin papilloma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	1	0	2
Vascular disorders			
Aortic arteriosclerosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Aortic disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood pressure fluctuation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0

Flushing			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	3
Hot flush			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Hypertension			
subjects affected / exposed	4 / 70 (5.71%)	4 / 60 (6.67%)	22 / 317 (6.94%)
occurrences (all)	4	4	24
Hypertensive angiopathy			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Hypertensive crisis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	3 / 317 (0.95%)
occurrences (all)	0	1	4
Hypotension			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	1	0	3
Thrombophlebitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Gestational diabetes			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Vomiting in pregnancy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
General disorders and administration site conditions			

Application site erythema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	3 / 70 (4.29%)	5 / 60 (8.33%)	11 / 317 (3.47%)
occurrences (all)	3	5	11
Axillary pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 70 (1.43%)	2 / 60 (3.33%)	5 / 317 (1.58%)
occurrences (all)	1	5	6
Chills			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Crying			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	2
Energy increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	6 / 70 (8.57%)	9 / 60 (15.00%)	27 / 317 (8.52%)
occurrences (all)	6	11	34
Feeling abnormal			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Feeling cold			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Feeling hot			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	1	0	6

Generalised oedema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hangover			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hyperthermia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	5
Inflammation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	3 / 317 (0.95%)
occurrences (all)	0	1	6
Irritability			
subjects affected / exposed	2 / 70 (2.86%)	2 / 60 (3.33%)	3 / 317 (0.95%)
occurrences (all)	2	2	4
Localised oedema			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Malaise			
subjects affected / exposed	1 / 70 (1.43%)	3 / 60 (5.00%)	3 / 317 (0.95%)
occurrences (all)	1	6	4
Mucosal dryness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	7 / 317 (2.21%)
occurrences (all)	0	0	9
Pain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	1	0	6
Pyrexia			
subjects affected / exposed	2 / 70 (2.86%)	2 / 60 (3.33%)	12 / 317 (3.79%)
occurrences (all)	2	3	14

Spinal pain subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	2 / 317 (0.63%) 3
Thirst subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Immune system disorders Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 60 (1.67%) 1	5 / 317 (1.58%) 6
Multiple allergies subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 60 (1.67%) 2	0 / 317 (0.00%) 0
Social circumstances Menopause subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Reproductive system and breast disorders Amenorrhoea subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	2 / 317 (0.63%) 2
Breast pain subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1

Cervical dysplasia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	0	0	5
Endometrial hyperplasia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Erectile dysfunction			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Fibrocystic breast disease			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Genital haemorrhage			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Menorrhagia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Menstruation irregular			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	3
Metrorrhagia			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	2	0	1
Oligomenorrhoea			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	2	0	3
Prostatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1

Prostatomegaly			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Pruritus genital			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Rectocele			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Scrotal cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Scrotal swelling			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Sexual dysfunction			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Spermatocele			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Testicular cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Testicular microlithiasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Uterine polyp			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0

Varicocele			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Atelectasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	8 / 317 (2.52%)
occurrences (all)	3	0	8
Dysphonia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	3 / 317 (0.95%)
occurrences (all)	2	2	3
Epistaxis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	5 / 317 (1.58%)
occurrences (all)	0	2	9
Hiccups			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hyperventilation			



subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Lung disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Nasal oedema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Nasal septum deviation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	3 / 317 (0.95%)
occurrences (all)	2	1	3
Pleurisy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Pneumonia aspiration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Pulmonary fibrosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Pulmonary vascular disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Reversible airways obstruction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Rhinorrhoea			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Stridor			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Vasomotor rhinitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Adjustment disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Affect lability			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Affective disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Aggression			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	1	0	2
Alcohol abuse			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	9 / 70 (12.86%)	3 / 60 (5.00%)	11 / 317 (3.47%)
occurrences (all)	11	3	12
Anxiety disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2

Apathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Bradyphrenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Bulimia nervosa			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Claustrophobia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	6 / 317 (1.89%)
occurrences (all)	1	0	8
Deja vu			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Delirium			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	1 / 70 (1.43%)	3 / 60 (5.00%)	4 / 317 (1.26%)
occurrences (all)	1	4	4
Depression			
subjects affected / exposed	4 / 70 (5.71%)	1 / 60 (1.67%)	6 / 317 (1.89%)
occurrences (all)	4	1	9
Disorientation			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Drug abuse			

subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Dysphemia			
subjects affected / exposed	0 / 70 (0.00%)	2 / 60 (3.33%)	0 / 317 (0.00%)
occurrences (all)	0	2	0
Dysphoria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Emotional disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hypervigilance			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Impaired reasoning			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	4 / 70 (5.71%)	2 / 60 (3.33%)	10 / 317 (3.15%)
occurrences (all)	4	2	11
Libido decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Mental disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Mood altered			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	1	1	1
Mood disorder due to a general			

medical condition			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Mood swings			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	6 / 317 (1.89%)
occurrences (all)	0	1	7
Nightmare			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	1	1	0
Panic attack			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	1	0	5
Panic disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Personality change			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Personality disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Psychogenic seizure			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Psychotic disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Restlessness			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	3
Sleep disorder			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	4 / 317 (1.26%)
occurrences (all)	0	2	4

Sleep talking			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Social avoidant behaviour			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Staring			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Suicidal ideation			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	2	0	1
Tachyphrenia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Tension			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Biliary dyskinesia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	2	0	1
Cholangitis acute			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cholecystitis chronic			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cholelithiasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Drug-induced liver injury			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hepatic pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	1	0	4
Hepatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hepatitis acute			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hepatomegaly			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hepatotoxicity			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Liver disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Investigations			

Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Alanine aminotransferase increased			
subjects affected / exposed	2 / 70 (2.86%)	2 / 60 (3.33%)	9 / 317 (2.84%)
occurrences (all)	2	2	10
Anti-gad antibody positive			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Anti-islet cell antibody positive			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 70 (2.86%)	2 / 60 (3.33%)	8 / 317 (2.52%)
occurrences (all)	2	2	8
Biopsy endometrium			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Blood 25-hydroxycholecalciferol decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood alkaline phosphatase decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	0	0	6
Blood bilirubin increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	3
Blood calcium increased			



subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	5 / 317 (1.58%)
occurrences (all)	0	0	5
Blood creatine phosphokinase increased			
subjects affected / exposed	4 / 70 (5.71%)	3 / 60 (5.00%)	14 / 317 (4.42%)
occurrences (all)	4	4	15
Blood creatinine decreased			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood folate decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Blood glucose increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 70 (0.00%)	2 / 60 (3.33%)	2 / 317 (0.63%)
occurrences (all)	0	2	2
Blood parathyroid hormone decreased			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	4
Blood phosphorus increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood potassium increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood pressure increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood sodium decreased			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Blood sodium increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	2
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood triglycerides			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Blood triglycerides increased			
subjects affected / exposed	0 / 70 (0.00%)	2 / 60 (3.33%)	6 / 317 (1.89%)
occurrences (all)	0	2	12
Blood urea increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Blood urine present			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Body mass index decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Body mass index increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Bone density increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	4 / 70 (5.71%)	1 / 60 (1.67%)	17 / 317 (5.36%)
occurrences (all)	5	1	22
Coagulation test abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Coagulation time prolonged			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Colonoscopy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Electrocardiogram qrs complex prolonged			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Electrocardiogram qt prolonged			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Eosinophil count decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Eosinophil count increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	6 / 70 (8.57%)	2 / 60 (3.33%)	48 / 317 (15.14%)
occurrences (all)	10	2	53
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	2
Haemoglobin decreased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	2	0	5
Heart rate decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Heart rate increased			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	1	0	2
High density lipoprotein decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	3
International normalised ratio decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	5 / 317 (1.58%)
occurrences (all)	0	0	6
Intraocular pressure increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Liver function test abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Monocyte count decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
N-telopeptide			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
N-telopeptide urine increased			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Neutrophil count increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Osteocalcin decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Osteocalcin increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Positive rombergism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Protein total increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Serum ferritin increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Tandem gait test abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Thyroid function test abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Thyroxine decreased			

subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	2	0	1
Thyroxine free decreased			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	4 / 317 (1.26%)
occurrences (all)	2	1	5
Transaminases increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	1	0	3
Tri-iodothyronine free increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Tri-iodothyronine increased			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Urine analysis abnormal			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Vitamin d decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Weight decreased			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	5 / 317 (1.58%)
occurrences (all)	0	1	5
Weight increased			
subjects affected / exposed	3 / 70 (4.29%)	0 / 60 (0.00%)	14 / 317 (4.42%)
occurrences (all)	3	0	14
White blood cell count decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
White blood cells urine positive			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Alcohol poisoning			

subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	1	0	2
Animal bite			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Ankle fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Brain contusion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Clavicle fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Contusion			
subjects affected / exposed	1 / 70 (1.43%)	2 / 60 (3.33%)	2 / 317 (0.63%)
occurrences (all)	1	2	2
Craniocerebral injury			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	0	1	2
Ear injury			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Excoriation			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	1	1	2
Expired drug administered			



subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Facial bones fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	8 / 317 (2.52%)
occurrences (all)	1	1	16
Foot fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Head injury			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Injury			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Joint injury			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	3
Ligament rupture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Ligament sprain			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Limb injury			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	4 / 317 (1.26%)
occurrences (all)	1	1	4
Lip injury			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	4	0	0
Nail injury			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Overdose			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	0	0	5
Scratch			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Soft tissue injury			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Thermal burn			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Thoracic vertebral fracture			

subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Tooth fracture subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Wrist fracture subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Congenital, familial and genetic disorders			
Bruton's agammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Congenital cerebrovascular anomaly subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 60 (1.67%) 1	0 / 317 (0.00%) 0
Cortical dysplasia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Gilbert's syndrome subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Hydrocele subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	2 / 317 (0.63%) 2
Aortic valve incompetence subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Arrhythmia			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Atrial fibrillation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	3
Atrial flutter			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Atrioventricular block			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block first degree			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	5 / 317 (1.58%)
occurrences (all)	0	0	5
Atrioventricular block second degree			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Bundle branch block left			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Bundle branch block right			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Cardiac disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cardiac failure			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cardiac failure chronic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cardiomyopathy			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cardiovascular disorder			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	2
Hypertensive heart disease			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Left atrial dilatation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Left ventricular hypertrophy			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Mitral valve prolapse			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Myocardial ischaemia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Palpitations			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	4 / 317 (1.26%)
occurrences (all)	0	2	4
Sinus bradycardia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	1	0	2
Sinus tachycardia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	0	0	4
Tachycardia paroxysmal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Action tremor			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Altered state of consciousness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Amnesia			
subjects affected / exposed	1 / 70 (1.43%)	2 / 60 (3.33%)	0 / 317 (0.00%)
occurrences (all)	1	2	0
Aphasia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Arachnoid cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Areflexia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Balance disorder			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	4
Burning sensation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Carotid artery stenosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Carpal tunnel syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Cerebrovascular accident			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	4
Cognitive disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Complex partial seizures			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Convulsion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Coordination abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Dementia alzheimer's type			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Disturbance in attention			

subjects affected / exposed	3 / 70 (4.29%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	4	0	4
Dizziness			
subjects affected / exposed	17 / 70 (24.29%)	19 / 60 (31.67%)	38 / 317 (11.99%)
occurrences (all)	24	37	54
Dysarthria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Dystonia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Epilepsy			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Epileptic aura			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Grand mal convulsion			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	2	0
Head discomfort			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	20 / 70 (28.57%)	24 / 60 (40.00%)	82 / 317 (25.87%)
occurrences (all)	38	57	159
Hemiparesis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hippocampal sclerosis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Hyperreflexia			



subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	1	0	2
Idiopathic generalised epilepsy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Incoherent			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Lumbar radiculopathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Lumbosacral plexus lesion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	2 / 70 (2.86%)	4 / 60 (6.67%)	9 / 317 (2.84%)
occurrences (all)	2	4	10
Mental impairment			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	6 / 317 (1.89%)
occurrences (all)	1	0	13
Monoparesis			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Myoclonus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	3
Paraesthesia			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	5 / 317 (1.58%)
occurrences (all)	2	1	5
Parosmia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	0	1	2
Peripheral nerve paresis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Postictal headache			
subjects affected / exposed	1 / 70 (1.43%)	2 / 60 (3.33%)	0 / 317 (0.00%)
occurrences (all)	1	3	0
Postictal paralysis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0

Postictal state			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Psychomotor hyperactivity			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Reflexes abnormal			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	0	1	3
Sedation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Sensory disturbance			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Simple partial seizures			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Slow speech			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	13 / 70 (18.57%)	5 / 60 (8.33%)	28 / 317 (8.83%)
occurrences (all)	18	12	34
Syncope			
subjects affected / exposed	1 / 70 (1.43%)	2 / 60 (3.33%)	9 / 317 (2.84%)
occurrences (all)	1	9	11
Tension headache			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	3 / 317 (0.95%)
occurrences (all)	2	3	4

Tongue biting subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Transient ischaemic attack subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Tremor subjects affected / exposed occurrences (all)	2 / 70 (2.86%) 14	3 / 60 (5.00%) 4	3 / 317 (0.95%) 3
Vascular encephalopathy subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Vertebrobasilar insufficiency subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Blood and lymphatic system disorders			
Agranulocytosis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	2 / 70 (2.86%) 3	2 / 60 (3.33%) 2	8 / 317 (2.52%) 8
Bicytopenia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Eosinophilia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Haemorrhagic anaemia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Hypochromic anaemia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Leukocytosis			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	2	0	4
Lymph node pain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	1	0	3
Lymphopenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	2	0	0
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	5 / 317 (1.58%)
occurrences (all)	0	0	5
Thrombocytosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Deafness neurosensory			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0

Ear congestion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Ear discomfort			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	0	2	2
Hearing impaired			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hyperacusis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Mastoid disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	5 / 317 (1.58%)
occurrences (all)	2	1	5
Vertigo			
subjects affected / exposed	4 / 70 (5.71%)	2 / 60 (3.33%)	18 / 317 (5.68%)
occurrences (all)	7	2	30
Vertigo positional			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1

Vestibular ataxia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Vestibular disorder subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Eye disorders			
Asthenopia subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Astigmatism subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Blepharitis subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Blindness transient subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Cataract subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	2 / 317 (0.63%) 2
Diplopia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 60 (1.67%) 1	1 / 317 (0.32%) 1
Dry eye subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 2
Eczema eyelids subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Eye haemorrhage			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Eye movement disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	0	1	3
Eyelid oedema			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Eyelids pruritus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Keratoconus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Myopia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Pterygium			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 70 (0.00%)	2 / 60 (3.33%)	5 / 317 (1.58%)
occurrences (all)	0	2	5
Visual impairment			



subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	1 / 60 (1.67%) 1	2 / 317 (0.63%) 2
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	3 / 317 (0.95%) 3
Abdominal distension subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Abdominal pain subjects affected / exposed occurrences (all)	3 / 70 (4.29%) 3	4 / 60 (6.67%) 4	9 / 317 (2.84%) 10
Abdominal pain upper subjects affected / exposed occurrences (all)	4 / 70 (5.71%) 29	3 / 60 (5.00%) 5	12 / 317 (3.79%) 13
Aphthous stomatitis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Breath odour subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Coeliac disease subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Colitis ulcerative subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Colonic polyp subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Constipation subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	1 / 60 (1.67%) 2	6 / 317 (1.89%) 6
Dental caries subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 60 (1.67%) 1	3 / 317 (0.95%) 4

Diarrhoea			
subjects affected / exposed	3 / 70 (4.29%)	3 / 60 (5.00%)	15 / 317 (4.73%)
occurrences (all)	9	5	24
Diverticulum intestinal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	6 / 317 (1.89%)
occurrences (all)	2	0	7
Duodenal ulcer			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Duodenogastric reflux			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	7 / 317 (2.21%)
occurrences (all)	0	0	8
Enteritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Erosive duodenitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Flatulence			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	2	0	0
Food poisoning			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1

Frequent bowel movements subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Gastric mucosa erythema subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Gastric ulcer subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Gastritis subjects affected / exposed occurrences (all)	2 / 70 (2.86%) 2	1 / 60 (1.67%) 1	2 / 317 (0.63%) 3
Gastritis erosive subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Gastroduodenitis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Haematochezia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Hiatus hernia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Hypoaesthesia oral subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Intestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 4

Irritable bowel syndrome			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Leukoplakia oral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	2	0	1
Nausea			
subjects affected / exposed	10 / 70 (14.29%)	13 / 60 (21.67%)	34 / 317 (10.73%)
occurrences (all)	20	22	49
Odynophagia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Oral mucosal blistering			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Pancreatic steatosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Pancreatitis chronic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Paraesthesia oral			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	1	1	1
Periodontal disease			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1

Polyp colorectal subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Proctalgia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Rectal haemorrhage subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Reflux gastritis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Salivary hypersecretion subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Tongue ulceration subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Tooth loss subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	10 / 317 (3.15%) 13
Vomiting subjects affected / exposed occurrences (all)	5 / 70 (7.14%) 7	5 / 60 (8.33%) 7	12 / 317 (3.79%) 21
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	2 / 70 (2.86%) 2	1 / 60 (1.67%) 1	1 / 317 (0.32%) 1
Alopecia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 60 (1.67%) 3	3 / 317 (0.95%) 3
Blister			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Dermal cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	4
Dermatitis acneiform			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Dermatitis allergic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	7 / 317 (2.21%)
occurrences (all)	0	0	7
Drug eruption			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Eczema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	0	0	4
Erythema			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	4 / 317 (1.26%)
occurrences (all)	0	1	7
Night sweats			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Photosensitivity reaction			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Pigmentation disorder			

subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	2	0	4
Pruritus generalised			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	1	0	3
Psoriasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	6 / 70 (8.57%)	2 / 60 (3.33%)	10 / 317 (3.15%)
occurrences (all)	6	2	11
Rash generalised			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Scar			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Seborrhoea			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Skin depigmentation			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Skin irritation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Skin reaction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Skin striae			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Subcutaneous nodule			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Sweat gland disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Toxic skin eruption			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			



Calculus urinary			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Haematuria			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	2	0	1
Leukocyturia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	3	0	4
Nocturia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Pyuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Renal cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Renal impairment			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0

Renal pain subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	2 / 317 (0.63%) 3
Urethral pain subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Urinary hesitation subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Urinary tract disorder subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Endocrine disorders			
Empty sella syndrome subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Hyperparathyroidism subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Hyperparathyroidism secondary subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	2 / 70 (2.86%) 2	3 / 60 (5.00%) 3	8 / 317 (2.52%) 8
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	3 / 70 (4.29%) 4	1 / 60 (1.67%) 1	9 / 317 (2.84%) 11
Arthritis			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Arthropathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	8 / 70 (11.43%)	3 / 60 (5.00%)	14 / 317 (4.42%)
occurrences (all)	9	5	15
Bone pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Costochondritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Intervertebral disc disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 70 (1.43%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	1	1	2
Joint crepitation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Limb asymmetry			

subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	2 / 70 (2.86%)	2 / 60 (3.33%)	2 / 317 (0.63%)
occurrences (all)	2	4	2
Muscle tightness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	4 / 317 (1.26%)
occurrences (all)	2	1	5
Musculoskeletal stiffness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	3 / 317 (0.95%)
occurrences (all)	3	1	3
Myokymia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	2	2
Myositis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	6 / 317 (1.89%)
occurrences (all)	1	0	6
Osteoarthritis			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Osteochondritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Osteochondrosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Osteoporosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Pain in extremity			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	9 / 317 (2.84%)
occurrences (all)	0	0	10
Periostitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Rheumatoid arthritis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Sle arthritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Soft tissue mass			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Spinal osteoarthritis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	3	0	0
Spondylolisthesis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Sympathetic posterior cervical			

syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Tenosynovitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	11 / 317 (3.47%)
occurrences (all)	2	0	12
Bronchopneumonia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cellulitis			

subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Cervicitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Diverticulitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Enterovirus infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Eye infection viral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Eyelid infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Fungal infection			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	3
Gardnerella infection			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	7 / 317 (2.21%)
occurrences (all)	0	1	8
Gastroenteritis viral			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	2
Gastrointestinal infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Gastrointestinal viral infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Genital abscess			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Gingival abscess			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Helicobacter infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hepatitis c			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hepatitis viral			



subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	5 / 70 (7.14%)	0 / 60 (0.00%)	19 / 317 (5.99%)
occurrences (all)	6	0	20
Laryngitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Lobar pneumonia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	8 / 70 (11.43%)	7 / 60 (11.67%)	37 / 317 (11.67%)
occurrences (all)	10	14	56
Oesophagitis bacterial			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Onychomycosis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	1	0	1
Oral herpes			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Oral infection			

subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Orchitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	2
Parotitis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	6 / 317 (1.89%)
occurrences (all)	2	0	12
Pharyngitis streptococcal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Proctitis chlamydial			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	4
Pyelonephritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	5 / 317 (1.58%)
occurrences (all)	2	1	5
Respiratory tract infection viral			

subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	8 / 317 (2.52%)
occurrences (all)	2	1	8
Rhinitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Salmonellosis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Salpingo-oophoritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 70 (0.00%)	2 / 60 (3.33%)	4 / 317 (1.26%)
occurrences (all)	0	2	5
Skin infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tinea manuum			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	3 / 317 (0.95%)
occurrences (all)	0	1	3
Tonsillitis streptococcal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			

subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3
Tooth infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	0	0	6
Tracheitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Tuberculosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	7 / 317 (2.21%)
occurrences (all)	2	1	11
Urethritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	11 / 317 (3.47%)
occurrences (all)	2	0	11
Urinary tract infection bacterial			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Vaginal infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	7 / 317 (2.21%)
occurrences (all)	0	0	10
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection			

subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	0 / 317 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 70 (2.86%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	2	1	1
Dehydration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Diabetes mellitus			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	2	0	1
Dyslipidaemia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	1	0	4
Folate deficiency			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	5 / 317 (1.58%)
occurrences (all)	2	0	5
Hyperglycaemia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	4 / 317 (1.26%)
occurrences (all)	2	0	5
Hyperinsulinism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	0	0	3

Hyperphagia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	2 / 317 (0.63%)
occurrences (all)	0	1	3
Hypocalcaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	2 / 317 (0.63%)
occurrences (all)	0	0	2
Hypochloraemia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	0 / 317 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	6 / 70 (8.57%)	3 / 60 (5.00%)	3 / 317 (0.95%)
occurrences (all)	7	3	3
Increased appetite			
subjects affected / exposed	2 / 70 (2.86%)	0 / 60 (0.00%)	3 / 317 (0.95%)
occurrences (all)	2	0	3
Metabolic disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	0 / 317 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	1 / 70 (1.43%)	0 / 60 (0.00%)	5 / 317 (1.58%)
occurrences (all)	1	0	5
Overweight			
subjects affected / exposed	0 / 70 (0.00%)	1 / 60 (1.67%)	1 / 317 (0.32%)
occurrences (all)	0	1	1
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 60 (0.00%)	1 / 317 (0.32%)
occurrences (all)	0	0	1

Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 60 (0.00%) 0	1 / 317 (0.32%) 1
Vitamin d deficiency subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 60 (0.00%) 0	2 / 317 (0.63%) 2

<b>Non-serious adverse events</b>	CBZ-CR 400 mg BID x Safety Set	CBZ-CR 600 mg BID x Safety Set	
Total subjects affected by non-serious adverse events subjects affected / exposed	55 / 61 (90.16%)	29 / 34 (85.29%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Haemangioma subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 1	
Haemangioma of liver subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Lipoma subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Lung neoplasm subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Melanocytic naevus subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Osteoma subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Ovarian granulosa-theca cell tumour subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Skin papilloma			

subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Uterine leiomyoma			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Aortic arteriosclerosis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Aortic disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Blood pressure fluctuation			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Haematoma			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	4 / 61 (6.56%)	2 / 34 (5.88%)	
occurrences (all)	5	2	
Hypertensive angiopathy			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hypertensive crisis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	



Thrombophlebitis subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 3	0 / 34 (0.00%) 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Gestational diabetes subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Vomiting in pregnancy subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
General disorders and administration site conditions			
Application site erythema subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Asthenia subjects affected / exposed occurrences (all)	2 / 61 (3.28%) 2	3 / 34 (8.82%) 4	
Axillary pain subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	0 / 34 (0.00%) 0	
Chest pain subjects affected / exposed occurrences (all)	2 / 61 (3.28%) 4	1 / 34 (2.94%) 1	
Chills subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 1	
Crying subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 1	
Energy increased subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Fatigue			

subjects affected / exposed	5 / 61 (8.20%)	6 / 34 (17.65%)
occurrences (all)	7	11
Feeling abnormal		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Feeling cold		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Feeling hot		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gait disturbance		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Generalised oedema		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hangover		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyperthermia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Inflammation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Influenza like illness		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Irritability		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Localised oedema		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Malaise		

subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Mucosal dryness			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Spinal pain			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Thirst			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Drug hypersensitivity			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hypersensitivity			
subjects affected / exposed	2 / 61 (3.28%)	1 / 34 (2.94%)	
occurrences (all)	2	1	
Multiple allergies			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Seasonal allergy			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	2	

Social circumstances			
Menopause			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Breast pain			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Cervical dysplasia			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Dysmenorrhoea			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Erectile dysfunction			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Fibrocystic breast disease			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Genital haemorrhage			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Menorrhagia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Menstruation irregular			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Metrorrhagia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Oligomenorrhoea		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Ovarian cyst		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Prostatitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Prostatomegaly		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pruritus genital		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Rectocele		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Scrotal cyst		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Scrotal swelling		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Sexual dysfunction		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Spermatocele		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Testicular cyst		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Testicular microlithiasis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Uterine polyp			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vaginal discharge			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vaginal haemorrhage			
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)	
occurrences (all)	2	0	
Varicocele			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Asthma			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Atelectasis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Bronchospasm			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Cough			

subjects affected / exposed	2 / 61 (3.28%)	1 / 34 (2.94%)
occurrences (all)	2	1
Dysphonia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Dyspnoea		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Epistaxis		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	2	0
Hiccups		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Hyperventilation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Lung disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Nasal congestion		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Nasal oedema		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Nasal septum deviation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Oropharyngeal pain		
subjects affected / exposed	2 / 61 (3.28%)	2 / 34 (5.88%)
occurrences (all)	2	6
Pleurisy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pneumonia aspiration		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Pulmonary fibrosis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Pulmonary vascular disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Reversible airways obstruction			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea			
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Stridor			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vasomotor rhinitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Adjustment disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Affect lability			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Affective disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	



Aggression		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Agitation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Alcohol abuse		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Anxiety		
subjects affected / exposed	3 / 61 (4.92%)	5 / 34 (14.71%)
occurrences (all)	6	5
Anxiety disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Apathy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Attention deficit/hyperactivity disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Bradyphrenia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Bulimia nervosa		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Claustrophobia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Confusional state		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Deja vu		

subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Delirium		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Depressed mood		
subjects affected / exposed	0 / 61 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	2
Depression		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Disorientation		
subjects affected / exposed	0 / 61 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	5
Drug abuse		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Dysphemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Dysphoria		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Emotional disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hallucination, auditory		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypervigilance		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Impaired reasoning		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Initial insomnia		

subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)
occurrences (all)	4	0
Insomnia		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Libido decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Mental disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Mood altered		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Mood disorder due to a general medical condition		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Mood swings		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Nervousness		
subjects affected / exposed	0 / 61 (0.00%)	4 / 34 (11.76%)
occurrences (all)	0	4
Nightmare		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Panic attack		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Panic disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Personality change		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0

Personality disorder		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Psychogenic seizure		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Psychotic disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Restlessness		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Sleep disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Sleep talking		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Social avoidant behaviour		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Staring		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Stress		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Suicidal ideation		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Tachyphrenia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tension		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0

Tic			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Biliary dyskinesia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Cholangitis acute			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Cholecystitis chronic			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Cholelithiasis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Drug-induced liver injury			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hepatic pain			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Hepatic steatosis			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Hepatitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hepatitis acute			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hepatomegaly			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hepatotoxicity			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Liver disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Anti-gad antibody positive			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Anti-islet cell antibody positive			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Biopsy endometrium			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Blood 25-hydroxycholecalciferol decreased			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase decreased			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	3	
Blood bilirubin increased			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Blood calcium decreased			
subjects affected / exposed	0 / 61 (0.00%)	2 / 34 (5.88%)	
occurrences (all)	0	2	
Blood calcium increased			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	2	
Blood chloride decreased			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Blood cholesterol increased			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 61 (4.92%)	2 / 34 (5.88%)	
occurrences (all)	3	2	
Blood creatinine decreased			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Blood folate decreased			

subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	2
Blood glucose decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood glucose increased		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Blood lactate dehydrogenase decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood parathyroid hormone decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood parathyroid hormone increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood phosphorus increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Blood potassium decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood potassium increased		
subjects affected / exposed	0 / 61 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	2
Blood pressure decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood pressure increased		



subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	2
Blood sodium decreased		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Blood sodium increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Blood thyroid stimulating hormone decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood thyroid stimulating hormone increased		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Blood triglycerides		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood triglycerides increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	4
Blood urea increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Blood urine present		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Body mass index decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Body mass index increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Body temperature increased		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Bone density increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
C-reactive protein increased		
subjects affected / exposed	3 / 61 (4.92%)	0 / 34 (0.00%)
occurrences (all)	4	0
Coagulation test abnormal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Coagulation time prolonged		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Colonoscopy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Electrocardiogram abnormal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Electrocardiogram qrs complex prolonged		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Electrocardiogram qt prolonged		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Eosinophil count decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eosinophil count increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	2
Gamma-glutamyltransferase abnormal		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gamma-glutamyltransferase increased		
subjects affected / exposed	9 / 61 (14.75%)	8 / 34 (23.53%)
occurrences (all)	11	12
Glomerular filtration rate decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Haematocrit decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Haemoglobin decreased		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Heart rate decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Heart rate increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Hepatic enzyme increased		
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)
occurrences (all)	2	0
High density lipoprotein decreased		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
International normalised ratio decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
International normalised ratio increased		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Intraocular pressure increased		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Liver function test abnormal		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Low density lipoprotein increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Lymphocyte count decreased		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Monocyte count decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
N-telopeptide		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
N-telopeptide urine increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Neutrophil count increased		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	2	0
Osteocalcin decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Osteocalcin increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Platelet count decreased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Positive rombergism		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Protein total decreased		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Protein total increased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Red blood cell count decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Serum ferritin increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tandem gait test abnormal		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Thyroid function test abnormal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Thyroxine decreased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Thyroxine free decreased		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Transaminases increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tri-iodothyronine free increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tri-iodothyronine increased		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Urine analysis abnormal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Vitamin d decreased		

subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Weight decreased			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Weight increased			
subjects affected / exposed	2 / 61 (3.28%)	3 / 34 (8.82%)	
occurrences (all)	2	3	
White blood cell count decreased			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
White blood cells urine positive			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Animal bite			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Ankle fracture			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Arthropod bite			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Arthropod sting			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Brain contusion			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Clavicle fracture			

subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Concussion		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Contusion		
subjects affected / exposed	2 / 61 (3.28%)	1 / 34 (2.94%)
occurrences (all)	2	1
Craniocerebral injury		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Ear injury		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Excoriation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Expired drug administered		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Face injury		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Facial bones fracture		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Fall		
subjects affected / exposed	1 / 61 (1.64%)	3 / 34 (8.82%)
occurrences (all)	1	3
Foot fracture		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hand fracture		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Head injury		

subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Injury		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Joint dislocation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Joint injury		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Laceration		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Ligament rupture		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Ligament sprain		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Limb injury		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Lip injury		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Muscle rupture		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Muscle strain		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Nail injury		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Overdose		



subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Scratch			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Skeletal injury			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Soft tissue injury			
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Thermal burn			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Wound			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Wrist fracture			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Bruton's agammaglobulinaemia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Congenital cerebrovascular anomaly			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Cortical dysplasia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Gilbert's syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Hydrocele			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Aortic valve incompetence			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Arrhythmia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Atrial fibrillation			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Atrial flutter			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Atrioventricular block			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Atrioventricular block first degree			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Atrioventricular block second degree			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	

Bradycardia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Bundle branch block left		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Bundle branch block right		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cardiac disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cardiac failure		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cardiac failure chronic		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cardiomyopathy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cardiovascular disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypertensive heart disease		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Left atrial dilatation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Left ventricular hypertrophy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Mitral valve incompetence		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0

Mitral valve prolapse subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Myocardial ischaemia subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Palpitations subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 1	
Sinus bradycardia subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	0 / 34 (0.00%) 0	
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Supraventricular extrasystoles subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Tachycardia subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 1	
Tachycardia paroxysmal subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Ventricular extrasystoles subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Nervous system disorders			
Action tremor subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Altered state of consciousness subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Amnesia			

subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Aphasia		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Arachnoid cyst		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Areflexia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Ataxia		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Autonomic nervous system imbalance		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Balance disorder		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	2
Burning sensation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Carotid artery stenosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Carpal tunnel syndrome		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cerebrovascular accident		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cerebrovascular disorder		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0

Cervicobrachial syndrome		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cognitive disorder		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Complex partial seizures		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Convulsion		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Coordination abnormal		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Dementia alzheimer's type		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Disturbance in attention		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Dizziness		
subjects affected / exposed	14 / 61 (22.95%)	13 / 34 (38.24%)
occurrences (all)	27	39
Dysarthria		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Dysgeusia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Dystonia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Epilepsy		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1

Epileptic aura		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Grand mal convulsion		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Head discomfort		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Headache		
subjects affected / exposed	22 / 61 (36.07%)	12 / 34 (35.29%)
occurrences (all)	46	57
Hemiparesis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hippocampal sclerosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyperreflexia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypersomnia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypoaesthesia		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Idiopathic generalised epilepsy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Incoherent		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Lethargy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0

Loss of consciousness		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Lumbar radiculopathy		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Lumbosacral plexus lesion		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Memory impairment		
subjects affected / exposed	0 / 61 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	3
Mental impairment		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Migraine		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	3
Monoparesis		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Muscle spasticity		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Myoclonus		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Neurotoxicity		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Nystagmus		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Paraesthesia		
subjects affected / exposed	3 / 61 (4.92%)	3 / 34 (8.82%)
occurrences (all)	15	14



Parosmia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Peripheral nerve paresis			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Poor quality sleep			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Postictal headache			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Postictal paralysis			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Postictal state			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	2	0	
Presyncope			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Psychomotor hyperactivity			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Reflexes abnormal			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sedation			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sensory disturbance			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Simple partial seizures			
subjects affected / exposed	2 / 61 (3.28%)	1 / 34 (2.94%)	
occurrences (all)	3	1	
Slow speech			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	8 / 61 (13.11%)	7 / 34 (20.59%)	
occurrences (all)	8	15	
Syncope			
subjects affected / exposed	2 / 61 (3.28%)	3 / 34 (8.82%)	
occurrences (all)	3	3	
Tension headache			
subjects affected / exposed	0 / 61 (0.00%)	2 / 34 (5.88%)	
occurrences (all)	0	3	
Tongue biting			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Transient ischaemic attack			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	1 / 61 (1.64%)	2 / 34 (5.88%)	
occurrences (all)	1	2	
Vascular encephalopathy			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			

Agranulocytosis		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	2	0
Anaemia		
subjects affected / exposed	3 / 61 (4.92%)	0 / 34 (0.00%)
occurrences (all)	3	0
Bicytopenia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eosinophilia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Haemorrhagic anaemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypochromic anaemia		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Leukocytosis		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Leukopenia		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	3	1
Lymph node pain		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Lymphadenopathy		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Lymphopenia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Neutropenia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0

Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Pancytopenia subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	0 / 34 (0.00%) 0	
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Ear and labyrinth disorders			
Deafness subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Deafness neurosensory subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Ear congestion subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Ear discomfort subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 1	
Ear pain subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Hearing impaired subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Hyperacusis subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Hypoacusis			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Mastoid disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Neurosensory hypoacusis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sudden hearing loss			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Vertigo			
subjects affected / exposed	5 / 61 (8.20%)	3 / 34 (8.82%)	
occurrences (all)	6	10	
Vertigo positional			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vestibular ataxia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vestibular disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Astigmatism			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Blepharitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	

Blindness transient		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cataract		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Conjunctivitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Diplopia		
subjects affected / exposed	0 / 61 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	4
Dry eye		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eczema eyelids		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eye haemorrhage		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eye movement disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eye oedema		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Eye pain		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Eyelid oedema		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Eyelids pruritus		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1

Glaucoma			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Keratoconus			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Myopia			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Pterygium			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	2 / 61 (3.28%)	4 / 34 (11.76%)	
occurrences (all)	2	5	
Visual impairment			
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			
subjects affected / exposed	1 / 61 (1.64%)	3 / 34 (8.82%)	
occurrences (all)	2	4	
Abdominal pain upper			
subjects affected / exposed	5 / 61 (8.20%)	4 / 34 (11.76%)	
occurrences (all)	7	4	
Aphthous stomatitis			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Breath odour		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Coeliac disease		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Colitis ulcerative		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Colonic polyp		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Constipation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Dental caries		
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)
occurrences (all)	3	0
Diarrhoea		
subjects affected / exposed	3 / 61 (4.92%)	1 / 34 (2.94%)
occurrences (all)	4	1
Diverticulum intestinal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Dry mouth		
subjects affected / exposed	1 / 61 (1.64%)	2 / 34 (5.88%)
occurrences (all)	2	2
Duodenal ulcer		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Duodenogastric reflux		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Dyspepsia		



subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)
occurrences (all)	3	0
Enteritis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Enterocolitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Erosive duodenitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eructation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Flatulence		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Food poisoning		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Frequent bowel movements		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gastric mucosa erythema		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gastric ulcer		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gastritis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gastritis erosive		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gastroduodenitis		

subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Haematochezia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Haemorrhoids		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Hiatus hernia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypoaesthesia oral		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	2
Intestinal haemorrhage		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Irritable bowel syndrome		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Leukoplakia oral		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Mouth ulceration		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Nausea		
subjects affected / exposed	5 / 61 (8.20%)	11 / 34 (32.35%)
occurrences (all)	9	26
Odynophagia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Oesophagitis		

subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Oral mucosal blistering		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Oral pain		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pancreatic steatosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pancreatitis chronic		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Paraesthesia oral		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Periodontal disease		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Polyp colorectal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Proctalgia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Rectal haemorrhage		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Reflux gastritis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Salivary hypersecretion		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Tongue ulceration		

subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Tooth loss			
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Toothache			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	5 / 61 (8.20%)	6 / 34 (17.65%)	
occurrences (all)	8	10	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Alopecia			
subjects affected / exposed	0 / 61 (0.00%)	2 / 34 (5.88%)	
occurrences (all)	0	2	
Blister			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Dermal cyst			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)	
occurrences (all)	2	0	
Dermatitis acneiform			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Dermatitis allergic			
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)	
occurrences (all)	2	0	
Drug eruption			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	

Dry skin		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eczema		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Erythema		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyperhidrosis		
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)
occurrences (all)	2	0
Night sweats		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Photosensitivity reaction		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pigmentation disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pruritus		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pruritus generalised		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Psoriasis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Rash		
subjects affected / exposed	2 / 61 (3.28%)	3 / 34 (8.82%)
occurrences (all)	3	4
Rash generalised		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0

Rash maculo-papular		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Rash papular		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Rash pruritic		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Scar		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Seborrhoea		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Seborrhoeic dermatitis		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Skin depigmentation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Skin exfoliation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Skin irritation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Skin lesion		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Skin reaction		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Skin striae		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0

Subcutaneous nodule			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sunburn			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sweat gland disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Swelling face			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Toxic skin eruption			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Leukocyturia			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Nephrolithiasis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Nocturia			

subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Pollakiuria			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Pyuria			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Renal colic			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Renal cyst			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Renal impairment			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Renal pain			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Urethral pain			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Urinary hesitation			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Urinary tract disorder			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Empty sella syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	



Hyperparathyroidism subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Hyperparathyroidism secondary subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 1	
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	3 / 34 (8.82%) 3	
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Arthralgia subjects affected / exposed occurrences (all)	2 / 61 (3.28%) 2	1 / 34 (2.94%) 4	
Arthritis subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	1 / 34 (2.94%) 3	
Arthropathy subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Back pain subjects affected / exposed occurrences (all)	4 / 61 (6.56%) 5	3 / 34 (8.82%) 3	
Bone pain subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	1 / 34 (2.94%) 1	
Bursitis subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0	0 / 34 (0.00%) 0	
Costochondritis			

subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Exostosis		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Flank pain		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Intervertebral disc disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Intervertebral disc protrusion		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Joint crepitation		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Joint swelling		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Limb asymmetry		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Muscle spasms		
subjects affected / exposed	3 / 61 (4.92%)	1 / 34 (2.94%)
occurrences (all)	3	1
Muscle tightness		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	2
Muscle twitching		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Muscular weakness		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Musculoskeletal chest pain		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Musculoskeletal pain		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Musculoskeletal stiffness		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Myalgia		
subjects affected / exposed	2 / 61 (3.28%)	1 / 34 (2.94%)
occurrences (all)	6	1
Myokymia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Myositis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Neck pain		
subjects affected / exposed	1 / 61 (1.64%)	2 / 34 (5.88%)
occurrences (all)	1	2
Osteoarthritis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Osteochondritis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Osteochondrosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Osteoporosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pain in extremity		
subjects affected / exposed	3 / 61 (4.92%)	1 / 34 (2.94%)
occurrences (all)	4	1
Periostitis		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sle arthritis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Soft tissue mass			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Spondylolisthesis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Sympathetic posterior cervical syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Tendonitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Tenosynovitis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Abdominal abscess			

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Acarodermatitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Acute sinusitis		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Acute tonsillitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Body tinea		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Bronchitis		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Bronchopneumonia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cellulitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cervicitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Cystitis		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	2	1
Diverticulitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Ear infection		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Enterovirus infection		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Erysipelas		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Escherichia urinary tract infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eye infection viral		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Eyelid infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Folliculitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Fungal infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Fungal skin infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gardnerella infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gastroenteritis		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Gastroenteritis viral		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Gastrointestinal infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gastrointestinal viral infection		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Genital abscess		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Gingival abscess		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Gingivitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Helicobacter infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Helminthic infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hepatitis c		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hepatitis viral		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Herpes dermatitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Herpes simplex		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Herpes zoster		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Influenza		
subjects affected / exposed	5 / 61 (8.20%)	1 / 34 (2.94%)
occurrences (all)	5	2
Laryngitis		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Lobar pneumonia		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Lower respiratory tract infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Nasopharyngitis		
subjects affected / exposed	5 / 61 (8.20%)	5 / 34 (14.71%)
occurrences (all)	5	6
Oesophagitis bacterial		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Onychomycosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Oral herpes		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Oral infection		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1
Orchitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Otitis media acute		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Parotitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Periodontitis		
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)
occurrences (all)	3	0
Pharyngitis		



subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pharyngitis streptococcal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pneumonia		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Proctitis chlamydial		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Pulpitis dental		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Pyelonephritis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Respiratory tract infection		
subjects affected / exposed	2 / 61 (3.28%)	1 / 34 (2.94%)
occurrences (all)	4	1
Respiratory tract infection viral		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Rhinitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Salmonellosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Salpingo-oophoritis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Sinusitis		
subjects affected / exposed	4 / 61 (6.56%)	0 / 34 (0.00%)
occurrences (all)	4	0
Skin infection		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Staphylococcal infection		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tinea cruris		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tinea manuum		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Tinea versicolour		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tonsillitis		
subjects affected / exposed	3 / 61 (4.92%)	1 / 34 (2.94%)
occurrences (all)	7	1
Tonsillitis streptococcal		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tooth abscess		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Tooth infection		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	3	1
Tracheitis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Tuberculosis		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Upper respiratory tract infection		
subjects affected / exposed	2 / 61 (3.28%)	1 / 34 (2.94%)
occurrences (all)	4	1
Urethritis		

subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)	
occurrences (all)	2	0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vaginal infection			
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	2 / 61 (3.28%)	0 / 34 (0.00%)	
occurrences (all)	3	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Diabetes mellitus			
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)	
occurrences (all)	0	0	
Dyslipidaemia			
subjects affected / exposed	2 / 61 (3.28%)	2 / 34 (5.88%)	
occurrences (all)	2	3	

Folate deficiency		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Gout		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypercholesterolaemia		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Hyperglycaemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyperinsulinism		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyperkalaemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyperlipidaemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyperphagia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypertriglyceridaemia		
subjects affected / exposed	1 / 61 (1.64%)	1 / 34 (2.94%)
occurrences (all)	1	1
Hypocalcaemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypochloraemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hypoglycaemia		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0

Hypokalaemia		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Hyponatraemia		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	2
Increased appetite		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Metabolic disorder		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Obesity		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Overweight		
subjects affected / exposed	1 / 61 (1.64%)	0 / 34 (0.00%)
occurrences (all)	1	0
Type 1 diabetes mellitus		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Type 2 diabetes mellitus		
subjects affected / exposed	0 / 61 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0
Vitamin d deficiency		
subjects affected / exposed	0 / 61 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	1

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 July 2012	Amendment#1 This Amendment No. 1 was prepared based on the experience made thus far in the study with investigators and patients which led the sponsor to reconsider some points in the protocol.
27 March 2015	Amendment #2 The objective of this amendment is to clarify the end of the double-blind study, permitting some subjects to early terminate or even skip their maintenance phase, so that the openlabel extension study (BIA-2093-311/EXT).

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported