



Clinical trial results:

A multicenter, randomized, double-blind, placebo-controlled, parallel-group clinical trial to assess efficacy and safety of the herbal medicinal product Sinupret extract coated tablets in patients with chronic rhinosinusitis

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2015-001952-31 |
| Trial protocol | DE |
| Global end of trial date | 23 August 2017 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 06 January 2023 |
| First version publication date | 06 January 2023 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | CRS-03 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Bionorica SE |
| Sponsor organisation address | Kerschensteinerstraße 11-15, Neumarkt, Germany, 92318 |
| Public contact | Head of cooperate communication, Bionorica SE, info@bionorica.de |
| Scientific contact | Head of Research and Development, Bionorica SE, research.development@bionorica.de |

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 | 19 June 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 23 August 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 23 August 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of the herbal medicinal product Sinupret extract versus placebo in the treatment of chronic rhinosinusitis (CRS) in adults.

Protection of trial subjects:

This study was conducted in compliance with the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice, including the archiving of essential documents.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 28 April 2016 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Poland: 363 |
| Country: Number of subjects enrolled | Germany: 209 |
| Worldwide total number of subjects | 572 |
| EEA total number of subjects | 572 |

Notes:

Subjects enrolled per age group

| | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 489 |
| From 65 to 84 years | 83 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

A total of 624 patients were enrolled; of these, 51 were not randomized and not treated. In total, 573 (91.8% of the enrolled population) patients were randomized, of whom 1 patient was not treated. In total, 285 patients were randomized to treatment with Sinupret extract (test IMP) and 287 patients to treatment with placebo.

Pre-assignment

Screening details:

The trial consists of a screening phase of up to 2 weeks (V1 to V2). Patients were required to have CRS symptoms for more than 52 weeks prior to enrolment, diagnosis of CRS confirmed by an ENT-specialist, and severe symptoms at screening and baseline (MSS of at least 10 points).

Period 1

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

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Placebo coated tablets

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

Dosage and administration details:

One tablet placebo three times a day.

| | |
|------------------|------------------|
| Arm title | Sinupret extract |
|------------------|------------------|

Arm description:

Sinupret extract coated tablet containing 160 mg native dry extract; 1 tablet tid.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Sinupret extract |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Sinupret extract coated tablet containing 160 mg native dry extract; 1 tablet tid for 16 weeks.

| Number of subjects in period 1 | Placebo | Sinupret extract |
|--|---------|------------------|
| Started | 287 | 285 |
| End of treatment | 259 | 257 |
| End of observation | 255 | 252 |
| Completed | 255 | 252 |
| Not completed | 32 | 33 |
| Adverse event, serious fatal | 1 | - |
| Consent withdrawn by subject | 11 | 6 |
| Extreme CRS-related pain symptomatology | 2 | 3 |
| Reasons not related to disease | 1 | 1 |
| Adverse event, non-fatal | 11 | 10 |
| Pregnancy | - | 1 |
| Non-compliance with study drug | 1 | 2 |
| Lost to follow-up | 4 | 4 |
| Progressive disease | 1 | 4 |
| Protocol deviation | - | 2 |

Baseline characteristics

Reporting groups

| | |
|--|------------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo coated tablets | |
| Reporting group title | Sinupret extract |
| Reporting group description: | |
| Sinupret extract coated tablet containing 160 mg native dry extract; 1 tablet tid. | |

| Reporting group values | Placebo | Sinupret extract | Total |
|---|---------|------------------|-------|
| Number of subjects | 287 | 285 | 572 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 244 | 245 | 489 |
| From 65-84 years | 43 | 40 | 83 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 46.4 | 45.9 | |
| standard deviation | ± 14.73 | ± 14.06 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 168 | 164 | 332 |
| Male | 119 | 121 | 240 |

End points

End points reporting groups

| | |
|---|------------------------|
| Reporting group title | Placebo |
| Reporting group description: Placebo coated tablets | |
| Reporting group title | Sinupret extract |
| Reporting group description: Sinupret extract coated tablet containing 160 mg native dry extract; 1 tablet tid. | |
| Subject analysis set title | Sinupret extract - FAS |
| Subject analysis set type | Full analysis |
| Subject analysis set description: All randomized patients with at least one documented application of IMP and with at least one observed post-baseline value for the primary efficacy variable (MSSINV). | |
| Subject analysis set title | Placebo - FAS |
| Subject analysis set type | Full analysis |
| Subject analysis set description: All randomized patients with at least one documented application of IMP and with at least one observed post-baseline value for the primary efficacy variable (MSSINV). | |
| Subject analysis set title | Sinupret extract - SAF |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: All patients who received at least one dose of trial medication; patients who were treated with more than one type of clinical trial medication by mistake were analyzed according to the clinical trial medication they received the longest. | |
| Subject analysis set title | Placebo - SAF |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: All patients who received at least one dose of trial medication; patients who were treated with more than one type of clinical trial medication by mistake were analyzed according to the clinical trial medication they received the longest. | |
| Subject analysis set title | Sinupret extract - PPS |
| Subject analysis set type | Per protocol |
| Subject analysis set description: All patients from the FAS without major protocol deviations. | |
| Subject analysis set title | Placebo - PPS |
| Subject analysis set type | Per protocol |
| Subject analysis set description: All patients from the FAS without major protocol deviations. | |
| Primary: MSS-INV | |
| End point title | MSS-INV |
| End point description: The primary efficacy endpoint was the MSS-INV at V7. | |
| End point type | Primary |
| End point timeframe: After 12 weeks of treatment (Visit 7). | |

| | | | | |
|--------------------------------------|---------------------------|----------------------|--|--|
| End point values | Sinupret extract - FAS | Placebo - FAS | | |
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 279 | 283 | | |
| Units: Score points | | | | |
| arithmetic mean (standard deviation) | 5.4 (\pm 3.34) | 5.6 (\pm 3.69) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Van Elteren test adjusted for centre |
| Comparison groups | Sinupret extract - FAS v Placebo - FAS |
| Number of subjects included in analysis | 562 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3192 |
| Method | Van Elteren test |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.73 |
| upper limit | 0.45 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs occurring between V2 (randomisation) and V8 (end of observation) are reported.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 20.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------|
| Reporting group title | Sinupret extract |
|-----------------------|------------------|

Reporting group description: -

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description: -

| Serious adverse events | Sinupret extract | Placebo | |
|---|------------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 285 (1.05%) | 5 / 287 (1.74%) | |
| number of deaths (all causes) | 0 | 1 | |
| number of deaths resulting from adverse events | 0 | 1 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Parathyroid tumour benign | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Transient ischaemic attack | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Meniere's disease | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung disorder | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Psychiatric disorders | | | |
| Adjustment disorder with depressed mood | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |

| | | | |
|---|---|---|--|
| Hyperparathyroidism alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 285 (0.00%) 0 / 0 0 / 0 | 1 / 287 (0.35%) 0 / 1 0 / 0 | |
| Musculoskeletal and connective tissue disorders Pathological fracture alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 285 (0.00%) 0 / 0 0 / 0 | 1 / 287 (0.35%) 0 / 1 0 / 0 | |

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

| Non-serious adverse events | Sinupret extract | Placebo | |
|---|--|--|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 113 / 285 (39.65%) | 116 / 287 (40.42%) | |
| Vascular disorders Circulatory collapse alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Hypertension alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Hypotension alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Thrombosis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 1 / 285 (0.35%) 1 0 / 285 (0.00%) 0 1 / 285 (0.35%) 1 | 1 / 287 (0.35%) 2 0 / 287 (0.00%) 0 1 / 287 (0.35%) 1 0 / 287 (0.00%) 0 | |
| Surgical and medical procedures | | | |

| | | | |
|---|----------------------|----------------------|--|
| Dental operation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 | 1 / 287 (0.35%) 1 | |
| Tooth extraction alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 | 1 / 287 (0.35%) 1 | |
| General disorders and administration site conditions Asthenia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 1 / 287 (0.35%) 1 | |
| Fatigue alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Malaise alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Mucosal dryness alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Oedema peripheral alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Pyrexia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 2 / 287 (0.70%) 2 | |
| Reproductive system and breast disorders | | | |

| | | | |
|---|----------------------|----------------------|--|
| Menstrual disorder alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Vulvovaginal inflammation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Cough alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 3 / 285 (1.05%) 3 | 4 / 287 (1.39%) 4 | |
| Dysphonia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 | 2 / 287 (0.70%) 2 | |
| Dyspnoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Epistaxis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 2 / 285 (0.70%) 2 | 1 / 287 (0.35%) 1 | |
| Nasal congestion alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 | 1 / 287 (0.35%) 1 | |
| Nasal obstruction alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 1 / 287 (0.35%) 1 | |
| Noninfective bronchitis alternative assessment type: Non- | | | |

| | | |
|---|-----------------|-----------------|
| systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Oropharyngeal pain | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 6 / 285 (2.11%) | 6 / 287 (2.09%) |
| occurrences (all) | 6 | 7 |
| Pharyngeal inflammation | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 2 / 287 (0.70%) |
| occurrences (all) | 1 | 2 |
| Pharyngeal oedema | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Pleurisy | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Rhinalgia | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Rhinorrhoea | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 3 / 285 (1.05%) | 3 / 287 (1.05%) |
| occurrences (all) | 3 | 3 |
| Throat irritation | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Upper respiratory tract inflammation | | |
| alternative assessment type: Non-systematic | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed occurrences (all) | 1 / 285 (0.35%) 1 | 0 / 287 (0.00%) 0 | |
| Psychiatric disorders Insomnia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 | 1 / 287 (0.35%) 1 | |
| Product issues Device failure alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 | 1 / 287 (0.35%) 1 | |
| Investigations Alanine aminotransferase increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Blood alkaline phosphatase increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Blood creatine increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Blood glucose increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Blood urea increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Body temperature decreased alternative assessment type: Non-systematic | 1 / 285 (0.35%) 1 0 / 285 (0.00%) 0 0 / 285 (0.00%) 0 0 / 285 (0.00%) 0 1 / 285 (0.35%) 1 | 1 / 287 (0.35%) 1 1 / 287 (0.35%) 1 1 / 287 (0.35%) 1 1 / 287 (0.35%) 1 0 / 287 (0.00%) 0 | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| C-reactive protein increased | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 2 / 287 (0.70%) | |
| occurrences (all) | 0 | 2 | |
| Eosinophil count increased | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 1 / 287 (0.35%) | |
| occurrences (all) | 1 | 1 | |
| Gamma-glutamyltransferase increased | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 285 (1.05%) | 2 / 287 (0.70%) | |
| occurrences (all) | 3 | 2 | |
| Haemoglobin decreased | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hepatic enzyme increased | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lymphocyte count increased | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Neutrophil count decreased | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Bone contusion | | | |
| alternative assessment type: Non-systematic | | | |

| | | |
|---|-----------------|-----------------|
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Concussion | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Contusion | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 0 / 287 (0.00%) |
| occurrences (all) | 2 | 0 |
| Fall | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Hand fracture | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Humerus fracture | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Ligament sprain | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 2 / 287 (0.70%) |
| occurrences (all) | 2 | 2 |
| Muscle injury | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Muscle strain | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |

| | | | |
|--|------------------|------------------|--|
| <p>Nail injury</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Tendon rupture</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Thermal burn</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Tooth fracture</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | | | |
| | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| | 0 | 1 | |
| | | | |
| | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| | 0 | 1 | |
| | | | |
| | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| | 0 | 1 | |
| | | | |
| | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| | 1 | 0 | |
| Cardiac disorders | | | |
| | | | |
| | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| | 0 | 1 | |
| Nervous system disorders | | | |
| | | | |
| | | | |
| | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| | 1 | 0 | |
| | | | |
| | | | |
| | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| | 1 | 0 | |
| | | | |
| | | | |
| | 21 / 285 (7.37%) | 14 / 287 (4.88%) | |
| | 27 | 17 | |
| Migraine | | | |

| | | | |
|---|-----------------|-----------------|--|
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 1 / 287 (0.35%) | |
| occurrences (all) | 3 | 4 | |
| Paraesthesia | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Radiculopathy | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Sciatica | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 1 / 287 (0.35%) | |
| occurrences (all) | 1 | 1 | |
| Sensory disturbance | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Somnolence | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 285 (1.05%) | 1 / 287 (0.35%) | |
| occurrences (all) | 4 | 1 | |
| Tension headache | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Trigeminal neuralgia | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 2 | |
| Blood and lymphatic system disorders | | | |
| Microcytic anaemia | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Neutropenia | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Thrombocytopenia | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Thrombocytosis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Ear and labyrinth disorders | | | |
| Ear congestion | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Ear discomfort | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 1 / 287 (0.35%) | |
| occurrences (all) | 2 | 1 | |
| Ear pain | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 1 / 287 (0.35%) | |
| occurrences (all) | 2 | 1 | |
| Tinnitus | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vertigo | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed occurrences (all) | 2 / 285 (0.70%) 3 | 1 / 287 (0.35%) 1 | |
| Eye disorders Eye pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Ocular hyperaemia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 285 (0.00%) 0 1 / 285 (0.35%) 1 | 1 / 287 (0.35%) 3 0 / 287 (0.00%) 0 | |
| Gastrointestinal disorders Abdominal discomfort alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Abdominal distension alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Abdominal pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Abdominal pain upper alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Breath odour alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Colitis alternative assessment type: Non-systematic | 0 / 285 (0.00%) 0 1 / 285 (0.35%) 1 1 / 285 (0.35%) 1 5 / 285 (1.75%) 5 1 / 285 (0.35%) 1 | 1 / 287 (0.35%) 1 0 / 287 (0.00%) 0 4 / 287 (1.39%) 5 6 / 287 (2.09%) 6 0 / 287 (0.00%) 0 | |

| | | |
|---|-----------------|-----------------|
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Diarrhoea | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 8 / 285 (2.81%) | 8 / 287 (2.79%) |
| occurrences (all) | 9 | 9 |
| Diverticulum intestinal | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Dry mouth | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Dyspepsia | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 3 / 287 (1.05%) |
| occurrences (all) | 2 | 3 |
| Dysphagia | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Flatulence | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 2 / 287 (0.70%) |
| occurrences (all) | 0 | 2 |
| Food poisoning | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 1 / 287 (0.35%) |
| occurrences (all) | 2 | 1 |
| Gastric disorder | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |

| | | |
|---|-----------------|-----------------|
| Gastritis | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gastrointestinal disorder | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gastrointestinal inflammation | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Gastrooesophageal reflux disease | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 1 / 287 (0.35%) |
| occurrences (all) | 1 | 1 |
| Haematochezia | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Lip swelling | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Nausea | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 4 / 285 (1.40%) | 0 / 287 (0.00%) |
| occurrences (all) | 4 | 0 |
| Toothache | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Vomiting | | |
| alternative assessment type: Non-systematic | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 4 / 285 (1.40%) | 0 / 287 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis allergic | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Erythema | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hyperhidrosis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 8 / 285 (2.81%) | 0 / 287 (0.00%) | |
| occurrences (all) | 8 | 0 | |
| Pruritus | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 2 / 287 (0.70%) | |
| occurrences (all) | 1 | 2 | |
| Psoriasis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 1 / 287 (0.35%) | |
| occurrences (all) | 1 | 1 | |
| Rash papular | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Rash pruritic | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|---|---|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Skin hypopigmentation</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Skin odour abnormal</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Urticaria</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 285 (0.00%)</p> <p>0</p> <p>0 / 285 (0.00%)</p> <p>0</p> <p>1 / 285 (0.35%)</p> <p>1</p> <p>1 / 285 (0.35%)</p> <p>1</p> | <p>1 / 287 (0.35%)</p> <p>1</p> <p>1 / 287 (0.35%)</p> <p>1</p> <p>0 / 287 (0.00%)</p> <p>0</p> <p>0 / 287 (0.00%)</p> <p>0</p> | |
| <p>Renal and urinary disorders</p> <p>Haematuria</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nephrolithiasis</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Urine odour abnormal</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 285 (0.35%)</p> <p>1</p> <p>1 / 285 (0.35%)</p> <p>1</p> <p>1 / 285 (0.35%)</p> <p>1</p> | <p>1 / 287 (0.35%)</p> <p>1</p> <p>1 / 287 (0.35%)</p> <p>1</p> <p>0 / 287 (0.00%)</p> <p>0</p> | |
| <p>Musculoskeletal and connective tissue disorders</p> <p>Arthralgia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Back pain</p> <p>alternative assessment type: Non-systematic</p> | <p>0 / 285 (0.00%)</p> <p>0</p> | <p>1 / 287 (0.35%)</p> <p>1</p> | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Musculoskeletal pain | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 2 / 287 (0.70%) | |
| occurrences (all) | 0 | 2 | |
| Musculoskeletal stiffness | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pain in extremity | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 2 / 287 (0.70%) | |
| occurrences (all) | 0 | 2 | |
| Spinal pain | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 1 / 287 (0.35%) | |
| occurrences (all) | 1 | 1 | |
| Infections and infestations | | | |
| Acute sinusitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 2 / 287 (0.70%) | |
| occurrences (all) | 1 | 2 | |
| Bronchitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 285 (1.05%) | 2 / 287 (0.70%) | |
| occurrences (all) | 3 | 2 | |
| Bronchitis viral | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Conjunctivitis | | | |
| alternative assessment type: Non-systematic | | | |

| | | |
|---|-----------------|-----------------|
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Cystitis | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 3 / 285 (1.05%) | 4 / 287 (1.39%) |
| occurrences (all) | 3 | 4 |
| Gastroenteritis | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |
| Gastroenteritis viral | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gastrointestinal infection | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Haemophilus infection | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Herpes zoster | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Infection | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) |
| occurrences (all) | 1 | 0 |
| Influenza | | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) |
| occurrences (all) | 0 | 1 |

| | | | |
|---|-----------------|-----------------|--|
| Laryngitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Nasal herpes | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Oral herpes | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 2 / 287 (0.70%) | |
| occurrences (all) | 1 | 2 | |
| Pharyngitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 5 / 287 (1.74%) | |
| occurrences (all) | 0 | 6 | |
| Pneumonia | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 1 / 287 (0.35%) | |
| occurrences (all) | 1 | 1 | |
| Respiratory tract infection viral | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 285 (0.70%) | 0 / 287 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Rotavirus infection | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Sinusitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin infection | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Soft tissue infection | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Tonsillitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper respiratory tract infection | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 6 / 285 (2.11%) | 4 / 287 (1.39%) | |
| occurrences (all) | 7 | 4 | |
| Urinary tract infection | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 285 (1.05%) | 0 / 287 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Viral infection | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 1 / 287 (0.35%) | |
| occurrences (all) | 1 | 1 | |
| Viral pharyngitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Viral upper respiratory tract infection | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 29 / 285 (10.18%) | 32 / 287 (11.15%) | |
| occurrences (all) | 30 | 35 | |
| Metabolism and nutrition disorders | | | |
| Fluid imbalance | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Hypercholesterolaemia | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 285 (0.00%) | 1 / 287 (0.35%) | |
| occurrences (all) | 0 | 1 | |
| Lactose intolerance | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 285 (0.35%) | 0 / 287 (0.00%) | |
| occurrences (all) | 1 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported