



Clinical trial results:

Safety and Efficacy Evaluation of Topical Moxidex Otic Solution in the Treatment of Acute Otitis Media with Otorrhea in Tympanostomy Tubes

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2018-000643-37 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 14 October 2011 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 23 August 2018 |
| First version publication date | 23 August 2018 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | C-09-033 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01071902 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Alcon Research Ltd |
| Sponsor organisation address | 6201 S. Freeway, Fort Worth, TX, United States, 76134 |
| Public contact | Ophthalmology Unit, Novartis Pharmaceuticals , + 44 0127666733385, linda.masson@novartis.com |
| Scientific contact | Ophthalmology Unit, Novartis Pharmaceuticals , + 44 0127666733385, linda.masson@novartis.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 14 October 2011 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 14 October 2011 |
| Global end of trial reached? | Yes |
| Global end of trial date | 14 October 2011 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the efficacy and safety of topical Moxidex for the treatment of subjects with acute otitis media with tympanostomy tubes (AOMT).

Protection of trial subjects:

Prior to the start of the study, the study protocol, the informed consent and assent documents, patient instruction sheets, the Investigator's Brochure, as well as any advertising materials used to recruit patients were submitted to institutional review boards (IRBs) and independent ethics committees (IECs). The IRB/IECs reviewed all documents and approved required documents; copies of the approval letters were provided to Alcon. Consistent with both the IRB/IEC's requirements and all applicable regulations, the Investigators periodically provided study updates to the IRB/IEC. A patient or parent/legal guardian (if necessary, a legally authorized representative) provided informed consent, and children signed an approved assent form when appropriate. This study was conducted in accordance with Good Clinical Practices (GCP) and the ethical principles that have their origins in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 06 April 2010 |
| 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 | United States: 345 |
| Country: Number of subjects enrolled | Canada: 55 |
| Worldwide total number of subjects | 400 |
| EEA total number of subjects | 0 |

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) | 177 |
| Children (2-11 years) | 220 |

| | |
|---------------------------|---|
| Adolescents (12-17 years) | 3 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 45 sites located in Canada (5) and the United States (40).

Pre-assignment

Screening details:

This reporting group includes all randomized subjects (400).

Period 1

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

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|------------------|
| Arm title | Moxidex Solution |
|------------------|------------------|

Arm description:

Moxifloxacin 0.5%/dexamethasone phosphate 0.1% otic solution, 4 drops twice daily (BID) for 7 days

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Moxifloxacin 0.5%/dexamethasone phosphate 0.1% otic solution |
| Investigational medicinal product code | |
| Other name | Moxidex |
| Pharmaceutical forms | Ear drops, solution |
| Routes of administration | Auricular use |

Dosage and administration details:

4 drops twice daily (BID) for 7 days

| | |
|------------------|-----------------------|
| Arm title | Moxifloxacin Solution |
|------------------|-----------------------|

Arm description:

Moxifloxacin hydrochloride 0.5% otic solution, 4 drops BID for 7 days

| | |
|--|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Moxifloxacin hydrochloride 0.5% otic solution |
| Investigational medicinal product code | |
| Other name | Moxifloxacin |
| Pharmaceutical forms | Ear drops, solution |
| Routes of administration | Auricular use |

Dosage and administration details:

4 drops BID for 7 days

| | |
|------------------|---------|
| Arm title | Vehicle |
|------------------|---------|

Arm description:

Moxifloxacin/dexamethasone phosphate otic solution vehicle, 4 drops BID for 7 days

| | |
|--|--|
| Arm type | Placebo |
| Investigational medicinal product name | Moxifloxacin/dexamethasone phosphate otic solution vehicle |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Ear drops, solution |
| Routes of administration | Auricular use |

| Number of subjects in period 1 | Moxidex Solution | Moxifloxacin Solution | Vehicle |
|---|------------------|-----------------------|---------|
| Started | 134 | 138 | 128 |
| Completed | 100 | 83 | 37 |
| Not completed | 34 | 55 | 91 |
| Treatment failure | 18 | 31 | 61 |
| Baseline culture results positive for Strep A | 2 | 4 | 2 |
| Adverse event, non-fatal | 10 | 16 | 17 |
| Inclusion/exclusion violation | 1 | - | 1 |
| Baseline culture results positive for yeast | - | 2 | 2 |
| Lost to follow-up | 1 | - | - |
| Other - Reason not given | 2 | 2 | 7 |
| Noncompliance | - | - | 1 |

Baseline characteristics

Reporting groups

| | |
|--|-----------------------|
| Reporting group title | Moxidex Solution |
| Reporting group description: | |
| Moxifloxacin 0.5%/dexamethasone phosphate 0.1% otic solution, 4 drops twice daily (BID) for 7 days | |
| Reporting group title | Moxifloxacin Solution |
| Reporting group description: | |
| Moxifloxacin hydrochloride 0.5% otic solution, 4 drops BID for 7 days | |
| Reporting group title | Vehicle |
| Reporting group description: | |
| Moxifloxacin/dexamethasone phosphate otic solution vehicle, 4 drops BID for 7 days | |

| Reporting group values | Moxidex Solution | Moxifloxacin Solution | Vehicle |
|---|------------------|-----------------------|---------|
| Number of subjects | 134 | 138 | 128 |
| Age categorical | | | |
| This analysis population includes all subjects who received study drug (Intent-to-Treat (ITT) Analysis Set) | | | |
| Units: Subjects | | | |
| Infants and toddlers (28 days-23 months) | 62 | 62 | 53 |
| Children (2-11 years) | 72 | 75 | 73 |
| Adolescents (12-17 years) | 0 | 1 | 2 |
| Gender categorical | | | |
| ITT Analysis Set | | | |
| Units: Subjects | | | |
| Female | 54 | 65 | 52 |
| Male | 80 | 73 | 76 |

| Reporting group values | Total | | |
|---|-------|--|--|
| Number of subjects | 400 | | |
| Age categorical | | | |
| This analysis population includes all subjects who received study drug (Intent-to-Treat (ITT) Analysis Set) | | | |
| Units: Subjects | | | |
| Infants and toddlers (28 days-23 months) | 177 | | |
| Children (2-11 years) | 220 | | |
| Adolescents (12-17 years) | 3 | | |
| Gender categorical | | | |
| ITT Analysis Set | | | |
| Units: Subjects | | | |
| Female | 171 | | |
| Male | 229 | | |

End points

End points reporting groups

| | |
|--|-----------------------|
| Reporting group title | Moxidex Solution |
| Reporting group description: Moxifloxacin 0.5%/dexamethasone phosphate 0.1% otic solution, 4 drops twice daily (BID) for 7 days | |
| Reporting group title | Moxifloxacin Solution |
| Reporting group description: Moxifloxacin hydrochloride 0.5% otic solution, 4 drops BID for 7 days | |
| Reporting group title | Vehicle |
| Reporting group description: Moxifloxacin/dexamethasone phosphate otic solution vehicle, 4 drops BID for 7 days | |

Primary: Clinical cure rate at Day 8

| | |
|--|--|
| End point title | Clinical cure rate at Day 8 ^[1] |
| End point description: Clinical cure was attained if the clinical response was resolved/cured (ie, absence of otorrhea) as evaluated by the Investigator at the end-of-therapy (EOT) visit. Reported as a percentage of subjects. This analysis population includes all subjects in the ITT population who were culture positive on Day 1 (Modified Intent-to-Treat (MITT) Analysis Set). Due to the study being cancelled, no statistical testing was performed. | |
| End point type | Primary |
| End point timeframe: Day 8 | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical testing was performed due to early termination of the study.

| End point values | Moxidex Solution | Moxifloxacin Solution | Vehicle | |
|-------------------------------|------------------|-----------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 96 | 91 | 98 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 68.8 | 60.4 | 16.3 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Cessation of Otorrhea

| | |
|--|-------------------------------|
| End point title | Time to Cessation of Otorrhea |
| End point description: Time to cessation of otorrhea was defined as the time (in days) to the absence of otorrhea (i.e. otorrhea was absent and remained absent) and was calculated as the number of days from first dose of study treatment to the absence of otorrhea as recorded by parent/guardian via the patient diary. MITT with non-missing data. Due to the study being cancelled, no statistical testing was performed. | |
| End point type | Secondary |

End point timeframe:

Up to Day 8

| End point values | Moxidex Solution | Moxifloxacin Solution | Vehicle | |
|-------------------------------|--------------------|-----------------------|--------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 96 | 91 | 97 | |
| Units: days | | | | |
| median (full range (min-max)) | 3.00 (0.0 to 18.0) | 4.00 (0.5 to 19.0) | 6.00 (0.5 to 17.0) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Microbiological success at Day 8 (EOT) by Treatment

| | |
|-----------------|---|
| End point title | Microbiological success at Day 8 (EOT) by Treatment |
|-----------------|---|

End point description:

Microbiological success was defined as eradication of pre-therapy pathogens at Day 8 (EOT). A subject with no clinical signs of acute otitis media with otorrhea in tympanostomy tubes (AOMT) (i.e. clinical response was resolved/cured) and presumed eradication of pre-therapy pathogens was considered a microbiological success. Reported as a percentage. MITT Analysis Set. Due to the study being cancelled, no statistical testing was performed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 8

| End point values | Moxidex Solution | Moxifloxacin Solution | Vehicle | |
|-------------------------------|------------------|-----------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 96 | 91 | 98 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 67.7 | 58.2 | 15.3 | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Adverse event reporting additional description:

This analysis population includes all subjects who received at least one dose of study drug (Safety Analysis Set).

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 20.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------|
| Reporting group title | Moxidex Solution |
|-----------------------|------------------|

Reporting group description:

Subjects treated with Moxidex solution

| | |
|-----------------------|-----------------------|
| Reporting group title | Moxifloxacin Solution |
|-----------------------|-----------------------|

Reporting group description:

Subjects treated with Moxifloxacin solution

| | |
|-----------------------|---------|
| Reporting group title | Vehicle |
|-----------------------|---------|

Reporting group description:

Subjects treated with Moxidex vehicle

| Serious adverse events | Moxidex Solution | Moxifloxacin Solution | Vehicle |
|---|------------------|-----------------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 138 (0.00%) | 0 / 128 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

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

| Non-serious adverse events | Moxidex Solution | Moxifloxacin Solution | Vehicle |
|---|-------------------|-----------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 44 / 134 (32.84%) | 39 / 138 (28.26%) | 41 / 128 (32.03%) |
| Injury, poisoning and procedural complications | | | |
| Injury | | | |
| subjects affected / exposed | 3 / 134 (2.24%) | 1 / 138 (0.72%) | 2 / 128 (1.56%) |
| occurrences (all) | 3 | 1 | 2 |
| Concussion | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 0 / 128 (0.00%) 0 |
| Periorbital haematoma subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 0 / 128 (0.00%) 0 |
| Post-traumatic pain subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 0 / 128 (0.00%) 0 |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 0 / 128 (0.00%) 0 |
| General disorders and administration site conditions Granuloma subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 138 (0.00%) 0 | 1 / 128 (0.78%) 1 |
| Pyrexia subjects affected / exposed occurrences (all) | 5 / 134 (3.73%) 5 | 6 / 138 (4.35%) 6 | 3 / 128 (2.34%) 3 |
| Malaise subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 0 / 128 (0.00%) 0 |
| Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all) | 4 / 134 (2.99%) 4 | 3 / 138 (2.17%) 3 | 1 / 128 (0.78%) 1 |
| Ear discomfort subjects affected / exposed occurrences (all) | 2 / 134 (1.49%) 2 | 0 / 138 (0.00%) 0 | 1 / 128 (0.78%) 1 |
| Otorrhoea subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 3 / 138 (2.17%) 3 | 2 / 128 (1.56%) 2 |
| Ear haemorrhage subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 138 (0.72%) 1 | 0 / 128 (0.00%) 0 |
| Hypoacusis | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 138 (0.00%) 0 | 1 / 128 (0.78%) 1 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 5 / 134 (3.73%) | 2 / 138 (1.45%) | 2 / 128 (1.56%) |
| occurrences (all) | 5 | 2 | 2 |
| Diarrhoea | | | |
| subjects affected / exposed | 4 / 134 (2.99%) | 1 / 138 (0.72%) | 3 / 128 (2.34%) |
| occurrences (all) | 4 | 1 | 3 |
| Abdominal discomfort | | | |
| subjects affected / exposed | 3 / 134 (2.24%) | 0 / 138 (0.00%) | 0 / 128 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 138 (0.00%) | 0 / 128 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 138 (0.00%) | 1 / 128 (0.78%) |
| occurrences (all) | 1 | 0 | 1 |
| Oral mucosal eruption | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 138 (0.72%) | 0 / 128 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 3 / 134 (2.24%) | 2 / 138 (1.45%) | 2 / 128 (1.56%) |
| occurrences (all) | 3 | 2 | 2 |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 1 / 138 (0.72%) | 0 / 128 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 138 (0.00%) | 1 / 128 (0.78%) |
| occurrences (all) | 1 | 0 | 1 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 138 (0.00%) | 0 / 128 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Rhinorrhoea | | | |

| | | | |
|--|----------------------|------------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 1 / 128 (0.78%) 1 |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 138 (0.72%) 1 | 0 / 128 (0.00%) 0 |
| Skin and subcutaneous tissue disorders Dermatitis diaper subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 1 / 128 (0.78%) 1 |
| Rash subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 0 / 128 (0.00%) 0 |
| Psychiatric disorders Irritability subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 138 (0.72%) 1 | 0 / 128 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Synovial cyst subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 0 / 128 (0.00%) 0 |
| Infections and infestations Otitis media subjects affected / exposed occurrences (all) | 5 / 134 (3.73%) 5 | 10 / 138 (7.25%) 10 | 9 / 128 (7.03%) 9 |
| Otitis media acute subjects affected / exposed occurrences (all) | 3 / 134 (2.24%) 3 | 6 / 138 (4.35%) 6 | 3 / 128 (2.34%) 3 |
| Ear infection subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 2 / 128 (1.56%) 2 |
| Otitis externa subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 138 (0.00%) 0 | 2 / 128 (1.56%) 2 |
| External ear cellulitis subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 138 (0.00%) 0 | 1 / 128 (0.78%) 1 |

| | | | |
|-----------------------------------|-----------------|-----------------|-----------------|
| Folliculitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 138 (0.00%) | 1 / 128 (0.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 3 / 134 (2.24%) | 1 / 138 (0.72%) | 3 / 128 (2.34%) |
| occurrences (all) | 3 | 1 | 3 |
| Conjunctivitis | | | |
| subjects affected / exposed | 2 / 134 (1.49%) | 0 / 138 (0.00%) | 2 / 128 (1.56%) |
| occurrences (all) | 2 | 0 | 2 |
| Croup infectious | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 1 / 138 (0.72%) | 0 / 128 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 138 (0.00%) | 3 / 128 (2.34%) |
| occurrences (all) | 1 | 0 | 3 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 138 (0.00%) | 0 / 128 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 2 / 138 (1.45%) | 0 / 128 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 2 / 138 (1.45%) | 0 / 128 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 138 (0.72%) | 0 / 128 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 138 (0.72%) | 0 / 128 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 138 (0.72%) | 0 / 128 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 138 (0.00%) | 1 / 128 (0.78%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 138 (0.72%) | 0 / 128 (0.00%) |
| occurrences (all) | 0 | 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