



Clinical trial results:

Double-blind, randomised clinical study comparing efficacy and safety of Ciclopirox Olamine Cream 10 mg/g (Test) vs. Batrafen® Cream (Reference) vs. Vehicle in patients with skin mycoses

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2018-001633-41 |
| Trial protocol | DE |
| Global end of trial date | 08 June 2021 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 08 June 2022 |
| First version publication date | 08 June 2022 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | 18-01/Cic-C |
|-----------------------|-------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Dermapharm AG |
| Sponsor organisation address | Lil-Dagover-Ring 7, Gruenwald, Germany, 82031 |
| Public contact | Clinical Research Department, Dermapharm AG, +49 89641860, Clinicaltrials.Dermapharm@dermapharm.com |
| Scientific contact | Clinical Research Department, Dermapharm AG, +49 89641860, Clinicaltrials.Dermapharm@dermapharm.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 20 April 2022 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 08 June 2021 |
| Global end of trial reached? | Yes |
| Global end of trial date | 08 June 2021 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Evaluation of the efficacy and safety of a new creme containing 10 mg/g Ciclopirox Olamine vs. the originator Batrafen® Cream (Reference) vs. vehicle in patients with skin mycoses

Protection of trial subjects:

There were no specific measures necessary.

Background therapy:

There was no background therapy.

Evidence for comparator:

The comparator contains the same ingredients in the same concentration as the test product and has a marketing license for the study indication.

| | |
|---|--------------|
| Actual start date of recruitment | 18 July 2019 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Germany: 403 |
| Worldwide total number of subjects | 403 |
| EEA total number of subjects | 403 |

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) | 296 |
| From 65 to 84 years | 105 |
| 85 years and over | 2 |

Subject disposition

Recruitment

Recruitment details:

14 study centers in Germany; first patient first visit: 05 August 2019; last patient last visit: 08 June 2021

Pre-assignment

Screening details:

Main criteria for inclusion:

Women and men ≥ 18 years of age; Diagnosis of skin mycosis confirmed by a positive microscopic native preparation in 30% potassium hydroxide (KOH); sum score of the parameters pruritus, burning/stinging, erythema, fissuring/cracking, scaling, and maceration up to a total score value of ≥ 6 (equal to moderate severity)

Period 1

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

Blinding implementation details:

The tubes containing the study medications were neutral white. The attached labels were identical for all three preparations. All three study medications were indistinguishable in terms of appearance. The random code was transferred to the data base not before the following actions were completed: data base closure, finalisation of the SAP, a Blind Data Review (BDR) and the agreement between sponsor and study statistician upon the definition of the analysis data sets (fixed in a BDR Report).

Arms

| | |
|------------------------------|-------|
| Are arms mutually exclusive? | Yes |
| Arm title | Cic-C |

Arm description:

Test product

| | |
|--|---------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Ciclopirox Olamin Cream 10 mg/g |
| Investigational medicinal product code | D01AE14 |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Application twice daily as a thin layer on the affected area

| | |
|------------------|----------|
| Arm title | Batrafen |
|------------------|----------|

Arm description:

Reference product

| | |
|--|------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Batrafen Cream 10 mg/g |
| Investigational medicinal product code | D01AE14 |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Application twice daily as a thin layer on the affected area

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

| | |
|--|---------------|
| Arm description: | |
| Vehicle of test product | |
| Arm type | Placebo |
| Investigational medicinal product name | Vehicle |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Application twice daily as a thin layer on the affected area.

| Number of subjects in period 1 | Cic-C | Batrafen | Vehicle |
|---------------------------------------|-------|----------|---------|
| Started | 129 | 141 | 133 |
| Completed | 120 | 129 | 117 |
| Not completed | 9 | 12 | 16 |
| Consent withdrawn by subject | 1 | - | 1 |
| Covid-related | 1 | 2 | 2 |
| Adverse event, non-fatal | 1 | 1 | - |
| Technical-logistic reasons | 2 | 3 | 5 |
| Poor tolerability | - | 1 | - |
| Lost to follow-up | 3 | 4 | 3 |
| Lack of efficacy | 1 | 1 | 5 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|------------------|
| Reporting group title | Treatment Period |
| Reporting group description: - | |

| Reporting group values | Treatment Period | Total | |
|--|------------------|-------|--|
| Number of subjects | 403 | 403 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 296 | 296 | |
| From 65-84 years | 105 | 105 | |
| 85 years and over | 2 | 2 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 133 | 133 | |
| Male | 270 | 270 | |

Subject analysis sets

| | |
|----------------------------|-----------------|
| Subject analysis set title | Safety data set |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Includes all randomised patients who had administered the study medication at least once and who provided at least one safety related outcome.

| | |
|----------------------------|---------------|
| Subject analysis set title | FAS |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Consists of all patients as randomised who received study medication at least once and have an assessment of the primary efficacy variable.

| | |
|----------------------------|--------------|
| Subject analysis set title | PP |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Comprises all patients of the FAS who did not exhibit any major protocol violations.

| Reporting group values | Safety data set | FAS | PP |
|--|-----------------|-----|-----|
| Number of subjects | 394 | 390 | 370 |
| 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) | 289 | 286 | 273 |
| From 65-84 years | 103 | 102 | 95 |
| 85 years and over | 2 | 2 | 2 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 127 | 126 | 121 |
| Male | 267 | 264 | 249 |

End points

End points reporting groups

| | |
|--|-----------------|
| Reporting group title | Cic-C |
| Reporting group description: | |
| Test product | |
| Reporting group title | Batrafen |
| Reporting group description: | |
| Reference product | |
| Reporting group title | Vehicle |
| Reporting group description: | |
| Vehicle of test product | |
| Subject analysis set title | Safety data set |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: | |
| Includes all randomised patients who had administered the study medication at least once and who provided at least one safety related outcome. | |
| Subject analysis set title | FAS |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Consists of all patients as randomised who received study medication at least once and have an assessment of the primary efficacy variable. | |
| Subject analysis set title | PP |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | |
| Comprises all patients of the FAS who did not exhibit any major protocol violations. | |

Primary: Clinical treatment success

| | |
|--|----------------------------|
| End point title | Clinical treatment success |
| End point description: | |
| The primary efficacy variable is clinical treatment success at the end-of-treatment examination at visit V4 (LOCF, i.e. last observation under treatment carried forward). Clinical treatment success was defined as 'yes' if the sum score of clinical parameters ≤ 2 AND all individual clinical score values ≤ 1 AND the mycological result was negative AND no further need for antimycotical treatment existed. | |
| End point type | Primary |
| End point timeframe: | |
| Start of treatment (visit 1) to EOT (visit 4) with 3 weeks treatment. | |

| End point values | Cic-C | Batrafen | Vehicle | |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 119 | 129 | 131 | |
| Units: Percentage | 45 | 66 | 46 | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Analysis of efficacy |
| Statistical analysis description: | |
| The primary objective of this study was to show therapeutic equivalence of the test preparation Cic-C compared to the approved reference Batrafen with respect to the primary efficacy variable. Therapeutic equivalence was statistically proven if the two-sided 95% confidence interval for $n_{Cic-C} - n_{Batrafen}$ was completely contained within $[-20\%, 20\%]$. | |
| Comparison groups | Batrafen v Cic-C |
| Number of subjects included in analysis | 248 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -13.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -26.42 |
| upper limit | -0.28 |

| | |
|---|----------------------------------|
| Statistical analysis title | Superiority of Test over Vehicle |
| Statistical analysis description: | |
| In order to verify assay sensitivity of the study, superiority of the two active preparations over the vehicle was tested by means of two-sided significance tests (Fisher's exact tests) with $\alpha = 5\%$. The primary test of superiority was carried out for the FAS data set. | |
| Comparison groups | Cic-C v Vehicle |
| Number of subjects included in analysis | 250 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.6053 |
| Method | Fisher exact |

| | |
|---|---------------------------------------|
| Statistical analysis title | Superiority of Reference over Vehicle |
| Statistical analysis description: | |
| In order to verify assay sensitivity of the study, superiority of the two active preparations over the vehicle was tested by means of two-sided significance tests (Fisher's exact tests) with $\alpha = 5\%$. The primary test of superiority was carried out for the FAS data set. | |
| Comparison groups | Batrafen v Vehicle |
| Number of subjects included in analysis | 260 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0132 |
| Method | Fisher exact |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the inclusion visit (V 1, day 0) to the final visit (V5, day 35, 2 weeks after EOT).

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------|
| Reporting group title | Cic-C |
|-----------------------|-------|

Reporting group description:

Test product

| | |
|-----------------------|----------|
| Reporting group title | Batrafen |
|-----------------------|----------|

Reporting group description:

Reference product

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

Reporting group description:

Vehicle of test product

| Serious adverse events | Cic-C | Batrafen | Vehicle |
|---|-----------------|-----------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 1 / 137 (0.73%) | 1 / 131 (0.76%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Circulatory collapse | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (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 |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 126 (0.00%) | 1 / 137 (0.73%) | 0 / 131 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 126 (0.00%) | 0 / 137 (0.00%) | 1 / 131 (0.76%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 0.05 %

| Non-serious adverse events | Cic-C | Batrafen | Vehicle |
|---|-------------------|------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 18 / 126 (14.29%) | 13 / 137 (9.49%) | 20 / 131 (15.27%) |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Application site dryness | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Application site erythema | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Application site pain | | | |
| subjects affected / exposed | 0 / 126 (0.00%) | 2 / 137 (1.46%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 2 | 1 |
| Application site paraesthesia | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Application site pruritus | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 1 / 126 (0.79%) | 0 / 137 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral swelling | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Swelling subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Xerosis subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Immune system disorders Allergy to chemicals subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Reproductive system and breast disorders Menstrual disorder subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Respiratory, thoracic and mediastinal disorders Nasal polyps subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Psychiatric disorders Depressed mood subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Injury, poisoning and procedural complications Skin laceration subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Nervous system disorders Burning sensation subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Headache | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 2 / 126 (1.59%) 2 | 1 / 137 (0.73%) 1 | 2 / 131 (1.53%) 2 |
| Paraesthesia subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 2 / 137 (1.46%) 2 | 0 / 131 (0.00%) 0 |
| Eye disorders Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 2 / 137 (1.46%) 2 | 0 / 131 (0.00%) 0 |
| Skin and subcutaneous tissue disorders Dermatitis contact subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Dry skin subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Eczema subjects affected / exposed occurrences (all) | 2 / 126 (1.59%) 2 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Intertrigo subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Pruritus subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Psoriasis subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Rosacea | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Skin exfoliation subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthritis subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 2 / 126 (1.59%) 2 | 2 / 137 (1.46%) 2 | 1 / 131 (0.76%) 1 |
| Infections and infestations COVID-19 subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Epididymitis subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Fungal infection subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 2 / 131 (1.53%) 3 |
| Fungal skin infection subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 2 |
| Groin abscess subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 4 / 131 (3.05%) 4 |
| Pulpitis dental | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 0 / 137 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Sinusitis subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 1 / 131 (0.76%) 1 |
| Tinea pedis subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 126 (0.00%) 0 | 1 / 137 (0.73%) 1 | 0 / 131 (0.00%) 0 |
| Metabolism and nutrition disorders Hypercholesterolaemia subjects affected / exposed occurrences (all) | 1 / 126 (0.79%) 1 | 0 / 137 (0.00%) 0 | 0 / 131 (0.00%) 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|---------------|
| None reported |
|---------------|

Notes: