



Clinical trial results:

Double blind, randomized, clinical study to compare the efficacy and safety of betamethasone 0,05%_salicyclic acid 2% solution vs.

Diprosalic solution vs. vehicle for the treatment of psoriasis capitis

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2010-024033-24 |
| Trial protocol | DE |
| Global end of trial date | 15 October 2013 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 14 February 2016 |
| First version publication date | 14 February 2016 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | 11-01/BSal-L |
|-----------------------|--------------|

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, 82031, Germany, Gruenwald |
| Public contact | Head of clinical department, Dermapharm AG, 0049 08964186-0, |
| Scientific contact | Head of clinical department, Dermapharm AG, 0049 08964186-0, |

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 | 23 April 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 15 October 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 15 October 2013 |
| 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 0,05% betamethasone 2% salicylic acid solution vs. the originator Diprosalic solution (licensed) vs. vehicle in patients with psoriasis of the scalp

Protection of trial subjects:

There were no specific measures necessary.

Background therapy:

There was no background therapy.

Evidence for comparator:

The trial aimed to show non-inferiority with regard to the comparator in order to obtain a generic marketing authorization for the test product.

| | |
|---|--------------|
| Actual start date of recruitment | 29 June 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 | Germany: 225 |
| Worldwide total number of subjects | 225 |
| EEA total number of subjects | 225 |

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) | 143 |
| From 65 to 84 years | 72 |
| 85 years and over | 10 |

Subject disposition

Recruitment

Recruitment details:

All study centres in Germany

First patient first visit: 04 July 2011

Last patient last visit: 15 October 2013

Pre-assignment

Screening details:

Main criteria for inclusion:

Women and men ≥ 18 years of age

Diagnosis of "scalp psoriasis" according to generally accepted criteria

Affection of at least 20% of the scalp

Affection of up to 50% or, in case of progression of psoriasis vulgaris during the last four weeks, up to 30% of the body surface

Score values as specified in the protocol

Period 1

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

Blinding implementation details:

All study preparations were indistinguishable in terms of appearance and were filled in white bottles of identical appearance.

Arms

| | |
|------------------------------|------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | BetaSal Solution |

Arm description:

Test product

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Betamethasone 0.05%_Salicylic Acid 2% Solution |
| Investigational medicinal product code | D07XC01 |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Twice per day. Total dose depends on the extent of the area to be treated.

| | |
|------------------|---------------------|
| Arm title | Diprosalic Solution |
|------------------|---------------------|

Arm description:

Reference product

| | |
|--|--------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Diprosalic |
| Investigational medicinal product code | D07XC01 |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Twice per day. Total dose depends on the extent of the area to be treated.

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

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

Dosage and administration details:

Twice per day. Total amount depends on the area to be treated.

| Number of subjects in period 1 | BetaSal Solution | Diprosalic Solution | Vehicle |
|--------------------------------|------------------|---------------------|---------|
| Started | 75 | 77 | 73 |
| Completed | 72 | 74 | 69 |
| Not completed | 3 | 3 | 4 |
| Adverse event, non-fatal | 1 | - | 1 |
| Technical-logistic reasons | 1 | - | - |
| Pregnancy | - | 1 | - |
| Lost to follow-up | 1 | - | - |
| Low cortisol values | - | 1 | - |
| Lack of efficacy | - | 1 | 3 |

Period 2

| | |
|------------------------------|--------------------------------|
| Period 2 title | Follow-up Period |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Monitor, Subject |

Blinding implementation details:

No treatment in the follow-up period.

Arms

| | |
|------------------------------|------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | BetaSal Solution |

Arm description:

Test product

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Betamethasone 0.05%_Salicylic Acid 2% Solution |
| Investigational medicinal product code | D07XC01 |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Twice per day. Total dose depends on the extent of the area to be treated.

| | |
|--|---------------------|
| Arm title | Diprosalic Solution |
| Arm description: | |
| Reference product | |
| Arm type | Active comparator |
| Investigational medicinal product name | Diprosalic |
| Investigational medicinal product code | D07XC01 |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Twice per day. Total dose depends on the extent of the area to be treated.

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

Dosage and administration details:

Twice per day. Total amount depends on the area to be treated.

| Number of subjects in period 2 | BetaSal Solution | Diprosalic Solution | Vehicle |
|---------------------------------------|------------------|---------------------|---------|
| Started | 72 | 74 | 69 |
| Completed | 70 | 71 | 62 |
| Not completed | 2 | 3 | 7 |
| Consent withdrawn by subject | 1 | 1 | - |
| Lost to follow-up | 1 | 1 | 2 |
| Lack of efficacy | - | 1 | 5 |

Baseline characteristics

Reporting groups

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

| Reporting group values | Treatment Period | Total | |
|--|------------------|-------|--|
| Number of subjects | 225 | 225 | |
| 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) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Adults (18 years and above) | 225 | 225 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 55.7 | | |
| full range (min-max) | 20 to 92 | - | |
| Gender categorical | | | |
| Total number of subjects | | | |
| Units: Subjects | | | |
| Female | 137 | 137 | |
| Male | 88 | 88 | |

Subject analysis sets

| | |
|---|--------------------|
| Subject analysis set title | ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: includes all patients of the safety data who comply with the study diagnosis (according to the associated inclusion criterion) and provide the baseline value and at least one post baseline value under treatment | |
| Subject analysis set title | PP |
| Subject analysis set type | Per protocol |
| Subject analysis set description: includes all patients of the ITT data set who do not exhibit any major protocol violations | |
| Subject analysis set title | Safety data |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: comprises all patients who had administered the study medication at least once | |

| Reporting group values | ITT | PP | Safety data |
|---|----------|-----|-------------|
| Number of subjects | 225 | 210 | 225 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 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) | 0 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Adults (18 years and above) | 225 | | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 55.7 | | |
| full range (min-max) | 20 to 92 | | |
| Gender categorical | | | |
| Total number of subjects | | | |
| Units: Subjects | | | |
| Female | 137 | 126 | 137 |
| Male | 88 | 84 | 88 |

End points

End points reporting groups

| | |
|--|---------------------|
| Reporting group title | BetaSal Solution |
| Reporting group description: | |
| Test product | |
| Reporting group title | Diprosalic Solution |
| Reporting group description: | |
| Reference product | |
| Reporting group title | Vehicle |
| Reporting group description: - | |
| Reporting group title | BetaSal Solution |
| Reporting group description: | |
| Test product | |
| Reporting group title | Diprosalic Solution |
| Reporting group description: | |
| Reference product | |
| Reporting group title | Vehicle |
| Reporting group description: - | |
| Subject analysis set title | ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| includes all patients of the safety data who comply with the study diagnosis (according to the associated inclusion criterion) and provide the baseline value and at least one post baseline value under treatment | |
| Subject analysis set title | PP |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | |
| includes all patients of the ITT data set who do not exhibit any major protocol violations | |
| Subject analysis set title | Safety data |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: | |
| comprises all patients who had administered the study medication at least once | |

Primary: Treatment effect

| | |
|--|------------------|
| End point title | Treatment effect |
| End point description: | |
| change of the sum score, defined as the sum of the score values of the individual activity parameters erythema, desquamation, thickening and pruritus, calculated as "value at visit 1 minus value at visit 4" | |
| End point type | Primary |
| End point timeframe: | |
| start of treatment (visit 1) and end of treatment (visit 4) | |

| End point values | BetaSal Solution | Diprosalic Solution | Vehicle | |
|-------------------------------|------------------|---------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 68 | 71 | 71 | |
| Units: sum score values | | | | |
| median (full range (min-max)) | 6 (1 to 11) | 6 (-1 to 11) | 2 (-2 to 10) | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Analysis of efficacy |
| Statistical analysis description: | |
| Non-inferiority test (one-sided test) with alpha = 2.5% (t-test model) and beta = 20%, based on the PP data set. The Non-Inferiority limit was set to 1.5 | |
| Comparison groups | Diprosalic Solution v BetaSal Solution |
| Number of subjects included in analysis | 139 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.35 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 1-sided |
| lower limit | -0.36 |

Other pre-specified: Superiority of Test over Vehicle

| | |
|--|---|
| End point title | Superiority of Test over Vehicle ^[1] |
| End point description: | |
| change of the sum score, defined as the sum of the score values of the individual activity parameters erythema, desquamation, thickening and pruritus, calculated as "value at visit 1 minus value at visit 4" | |
| End point type | Other pre-specified |
| End point timeframe: | |
| start of treatment (visit 1) and end of treatment (visit 4) | |

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The statistical analysis for this end point served as verification of the assay sensitivity and had to be done individually for each active preparation in accordance with CPMP/EWP/908/99.

| End point values | BetaSal Solution | Vehicle | | |
|-----------------------------|------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 75 | 73 | | |
| Units: sum score values | | | | |
| number (not applicable) | 5.9 | 2.27 | | |

Statistical analyses

| | |
|--|----------------------------|
| Statistical analysis title | Sensitivity analysis |
| Statistical analysis description: | |
| Superiority of Test over Vehicle for the primary efficacy variable | |
| Comparison groups | BetaSal Solution v Vehicle |
| Number of subjects included in analysis | 148 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | ANCOVA |

Other pre-specified: Superiority of Reference over Vehicle

| | |
|--|--|
| End point title | Superiority of Reference over Vehicle ^[2] |
| End point description: | |
| change of the sum score, defined as the sum of the score values of the individual activity parameters erythema, desquamation, thickening and pruritus, calculated as "value at visit 1 minus value at visit 4" | |
| End point type | Other pre-specified |
| End point timeframe: | |
| start of treatment (visit 1) and end of treatment (visit 4) | |

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The statistical analysis for this end point served as verification of the assay sensitivity and had to be done individually for each active preparation in accordance with CPMP/EWP/908/99.

| End point values | Diprosalic Solution | Vehicle | | |
|-----------------------------|---------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 77 | 73 | | |
| Units: sum score values | | | | |
| number (not applicable) | 5.37 | 2.29 | | |

Statistical analyses

| | |
|---|-------------------------------|
| Statistical analysis title | Sensitivity analysis |
| Comparison groups | Diprosalic Solution v Vehicle |
| Number of subjects included in analysis | 150 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | ANCOVA |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

from the inclusion visit (visit 0) to the final visit (visit 5)

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 16.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------|
| Reporting group title | BetaSal Solution |
|-----------------------|------------------|

Reporting group description:

Treatment arm with test product

| | |
|-----------------------|---------------------|
| Reporting group title | Diprosalic Solution |
|-----------------------|---------------------|

Reporting group description:

Treatment arm with reference product

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

Reporting group description:

Treatment arm with placebo

| Serious adverse events | BetaSal Solution | Diprosalic Solution | Vehicle |
|---|------------------|---------------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 75 (0.00%) | 2 / 77 (2.60%) | 0 / 73 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Alcohol poisoning | | | |
| subjects affected / exposed | 0 / 75 (0.00%) | 1 / 77 (1.30%) | 0 / 73 (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 |
| Infections and infestations | | | |
| Urinary tract infection staphylococcal | | | |
| subjects affected / exposed | 0 / 75 (0.00%) | 1 / 77 (1.30%) | 0 / 73 (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 |

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

| Non-serious adverse events | BetaSal Solution | Diprosalic Solution | Vehicle |
|---|------------------|---------------------|------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 12 / 75 (16.00%) | 10 / 77 (12.99%) | 13 / 73 (17.81%) |
| Investigations | | | |
| Blood glucose increased | | | |
| subjects affected / exposed | 1 / 75 (1.33%) | 2 / 77 (2.60%) | 0 / 73 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 75 (0.00%) | 1 / 77 (1.30%) | 0 / 73 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 75 (0.00%) | 1 / 77 (1.30%) | 0 / 73 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood cortisol increased | | | |
| subjects affected / exposed | 1 / 75 (1.33%) | 0 / 77 (0.00%) | 2 / 73 (2.74%) |
| occurrences (all) | 1 | 0 | 2 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Skin papilloma | | | |
| subjects affected / exposed | 1 / 75 (1.33%) | 0 / 77 (0.00%) | 0 / 73 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Seborrhoeic keratosis | | | |
| subjects affected / exposed | 1 / 75 (1.33%) | 0 / 77 (0.00%) | 0 / 73 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Arthropod sting | | | |
| subjects affected / exposed | 0 / 75 (0.00%) | 1 / 77 (1.30%) | 0 / 73 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 75 (1.33%) | 1 / 77 (1.30%) | 0 / 73 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 1 / 75 (1.33%) | 0 / 77 (0.00%) | 1 / 73 (1.37%) |
| occurrences (all) | 1 | 0 | 1 |
| General disorders and administration site conditions | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| Application site pain subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 2 / 73 (2.74%) 2 |
| Application site pruritus subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Application site dryness subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Eye disorders | | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 1 / 75 (1.33%) 1 | 0 / 77 (0.00%) 0 | 0 / 73 (0.00%) 0 |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Gastrointestinal disorders | | | |
| Nausea subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 73 (0.00%) 0 |
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 73 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Hyperkeratosis subjects affected / exposed occurrences (all) | 1 / 75 (1.33%) 1 | 0 / 77 (0.00%) 0 | 0 / 73 (0.00%) 0 |
| Skin tightness subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Eczema subjects affected / exposed occurrences (all) | 1 / 75 (1.33%) 1 | 0 / 77 (0.00%) 0 | 0 / 73 (0.00%) 0 |
| Rosacea | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Dermatitis subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 73 (0.00%) 0 |
| Skin burning sensation subjects affected / exposed occurrences (all) | 1 / 75 (1.33%) 1 | 0 / 77 (0.00%) 0 | 0 / 73 (0.00%) 0 |
| Polymorphic light eruption subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 73 (0.00%) 0 |
| Renal and urinary disorders Hydronephrosis subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 73 (0.00%) 0 |
| Cystitis noninfective subjects affected / exposed occurrences (all) | 1 / 75 (1.33%) 1 | 0 / 77 (0.00%) 0 | 0 / 73 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Trigger finger subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 2 / 75 (2.67%) 2 | 1 / 77 (1.30%) 1 | 2 / 73 (2.74%) 2 |
| Gastroenteritis subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 73 (0.00%) 0 |
| Bronchitis subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 0 / 77 (0.00%) 0 | 1 / 73 (1.37%) 1 |
| Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all) | 0 / 75 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 73 (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

None reported