# Clinical trial results:
# Assessment of the efficacy of a new formulation of minoxidil (DC120) on hair growth, in a minizone model in androgenetic alopecia in men

## Summary

| | |
|---|---|
| EudraCT number | 2014-005573-36 |
| Trial protocol | DE |
| Global end of trial date | 28 April 2016 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 16 December 2018 |
| First version publication date | 16 December 2018 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | DC0120LE202 |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Pierre Fabre |
| Sponsor organisation address | 45 place Abel Gance, Boulogne, France, 92654 |
| Public contact | Françoise TONNER, Pierre Fabre Dermatologie represented by the Institut de Recherche Pierre Fabre (IRPF), +33 (0)534 50 62 50, francoise.tonner@pierre-fabre.com |
| Scientific contact | Françoise TONNER, Pierre Fabre Dermatologie represented by the Institut de Recherche Pierre Fabre (IRPF), +33 (0)534 50 62 50, francoise.tonner@pierre-fabre.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 | 05 July 2016 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 28 April 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 April 2016 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of the study was to demonstrate the non-inferiority of DC0120 (Minoxidil 5%) cutaneous solution on hair growth, versus a reference product (ALOSTIL®; 5% cutaneous solution) in the treatment of Androgenetic Alopecia (AGA), over 16 weeks.

Protection of trial subjects:

The study was performed in accordance with the current version of the Declaration of Helsinki (1964 andits subsequent amendments). The study was conducted in agreement with the International Conferenceon Harmonisation (ICH) guidelines on Good Clinical Practice (GCP), and with related national regulation in biomedical research.
The first study protocol in use (V2, 28 May 2015), and the patient information sheets were reviewed and approved by the BfArM. There were no substantial subsequent amendments.
Patients were free to withdraw from the study at any time for any reason. The investigator could decide to withdraw a patient from the study due to tolerability/safety/efficacy issues if it was felt to be in the patient’s best interests

Background therapy:

No additional therapy was given during the study.

Evidence for comparator:

ALOPEXY® 5% (DC0120) cutaneous solution is a generic of REGAINE® 5% solution already registered in Europe. REGAINE® has been marketed in several European countries for many years, and is also registered and marketed in France since 1995, under the trade name of ALOSTIL® 5%. The composition of ALOPEXY® 5% cutaneous solution is similar to that of the reference product. In compliance with the ICH Guidelines (E9-Feb 1998) placebo was to be added in this design in order to test the assay sensitivity by confirming the efficacy of the active reference versus placebo in the current trial. As the 2 formulations had a different appearance, a double placebo design had to be used.

| | |
|---|---|
| Actual start date of recruitment | 01 June 2015 |
| 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: 220 |
| Worldwide total number of subjects | 220 |
| EEA total number of subjects | 220 |

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) | 220 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

A total of 231 patients were screened and 220 met the inclusion criteria and were randomised as planned to one of the 4 combination group, in 4 investigational centres in Germany. There were 11 screen failures: 7 patients were not pre-included (they did not meet all eligibility criteria or they decided not to participate), and 4 were not randomised

### Pre-assignment

Screening details:

Male subjects aged 18-65 years suffering from frontoemporal androgenetic alopecia, accepting to have 2 shaved and tattooed minizones on the scalp, with no historical of skin scalp abnormalities with a potential impact on the treatment response. The patients with a phototype > IV were not included in the study.

### 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, Data analyst, Assessor |

Blinding implementation details:

As the ALOSTIL® marketed form was the reference product in the study, a double placebo was used in order to obtain the double blind conditions, ensured by:
similar solutions for cutaneous application in 60 mL-bottles of DC0120 (minoxidil 5%) and placebo of DC0120;
similar solutions for cutaneous application in 60 mL-bottles of the marketed solution ALOSTIL® and its placebo.
Patients were provided wtih 1 blue case of treatment for the left side and one red case for the right side

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | DC120-Placebo of Alostil |

Arm description: -

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

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area. Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the frontal area of the scalp.
The application side of the 2 study treatments was randomised.

| | |
|---|---|
| Investigational medicinal product name | DC0120 (Minoxidil 5%) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area.
Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the

frontal area of the scalp. The application side of the 2 study treatments was randomised.

| **Arm title** | DC0120-Alostil |
|---|---|

Arm description:

All patients applied for 16 weeks (Day 1 [V2] to Day 110 ± 3 days [V9]) minoxidil 5% ( DC0120) solution and Alostil solution (one product on each side). The study product DC0120, the reference product ALOSTIL® and the corresponding placebos were randomised between 2 contra-lateral zones, the right and left sides of the frontal areas of the scalp using an incomplete block design. For training purposes, the patient applied the products the first day and 2 more days after within the 5 days after the first application at the Investigational Centre (in the morning or at the end of afternoon) under supervision of a trained person different from the investigator.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | DC0120 (Minoxidil 5%) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area.
Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the frontal area of the scalp. The application side of the 2 study treatments was randomised.

| Investigational medicinal product name | Alostil |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area. Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the frontal area of the scalp.
The application side of the 2 study treatments was randomised.

| **Arm title** | Alostil-placebo DC120 |
|---|---|

Arm description: -

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | Alostil |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area. Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the frontal area of the scalp.
The application side of the 2 study treatments was randomised.

| Investigational medicinal product name | Placebo DC0120 |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area.
Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the frontal area of the scalp. The application side of the 2 study treatments was randomised.

| **Arm title** | placebo DC0120-placebo Alostil |
|---|---|
| Arm description: - | |
| Arm type | Placebo |
| Investigational medicinal product name | Placebo DC0120 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area.
Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the frontal area of the scalp. The application side of the 2 study treatments was randomised.

| | |
|---|---|
| Investigational medicinal product name | Placebo of Alostil |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous solution |
| Routes of administration | Cutaneous use |

Dosage and administration details:

0.1 mL (for approximately 10 cm²), 2 applications per day (morning and evening; at least 8 hours apart) on one randomised test area. Cutaneous applications performed with a 0.6 mL single-use dose dispensing syringe and gentle massage, according to the randomisation scheme on 1 of the 2 target zones (about 10 cm2) on the frontal area of the scalp.
The application side of the 2 study treatments was randomised.

| **Number of subjects in period 1** | DC120-Placebo of Alostil | DC0120-Alostil | Alostil-placebo DC120 |
|---|---|---|---|
| Started | 44 | 110 | 44 |
| Completed | 42 | 104 | 42 |
| Not completed | 2 | 6 | 2 |
| Consent withdrawn by subject | - | - | 1 |
| Adverse event, non-fatal | 1 | 3 | - |
| Personal reason | 1 | 3 | 1 |

| **Number of subjects in period 1** | placebo DC0120-placebo Alostil |
|---|---|
| Started | 22 |
| Completed | 22 |
| Not completed | 0 |
| Consent withdrawn by subject | - |
| Adverse event, non-fatal | - |
| Personal reason | - |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | DC120-Placebo of Alostil |
| Reporting group description: - | |
| Reporting group title | DC0120-Alostil |

Reporting group description:

All patients applied for 16 weeks (Day 1 [V2] to Day 110 ± 3 days [V9]) minoxidil 5% ( DC0120) solution and Alostil solution (one product on each side). The study product DC0120, the reference product ALOSTIL® and the corresponding placebos were randomised between 2 contra-lateral zones, the right and left sides of the frontal areas of the scalp using an incomplete block design. For training purposes, the patient applied the products the first day and 2 more days after within the 5 days after the first application at the Investigational Centre (in the morning or at the end of afternoon) under supervision of a trained person different from the investigator.

| | |
|---|---|
| Reporting group title | Alostil-placebo DC120 |
| Reporting group description: - | |
| Reporting group title | placebo DC0120-placebo Alostil |

Reporting group description: -

| Reporting group values | DC120-Placebo of Alostil | DC0120-Alostil | Alostil-placebo DC120 |
|---|---|---|---|
| Number of subjects | 44 | 110 | 44 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 44 | 110 | 44 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous<br>Units: years | | | |
| median | 41.0 | 44.0 | 39.5 |
| full range (min-max) | 19.0 to 62.0 | 31.0 to 51.0 | 31.0 to 45.0 |
| Gender categorical<br>Units: Subjects | | | |
| Male | 44 | 110 | 44 |
| Nordwood Hamilton Scale<br>Units: Subjects | | | |
| 03 | 12 | 36 | 10 |
| 03A | 4 | 10 | 7 |
| 03V | 15 | 40 | 16 |
| 04 | 13 | 23 | 10 |
| 04A | 0 | 1 | 1 |
| Smoker status<br>Units: Subjects | | | |
| No smoker | 29 | 73 | 33 |
| Smoker | 15 | 37 | 11 |
| Fitzpatricks Classification<br>Units: Subjects | | | |
| 01 | 1 | 0 | 1 |
| 02 | 20 | 36 | 15 |
| 03 | 19 | 69 | 25 |
| 04 | 4 | 5 | 3 |

| Reporting group values | placebo DC0120-placebo Alostil | Total | |
|---|---|---|---|
| Number of subjects | 22 | 220 | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 22 | 220 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous<br>Units: years | | | |
| median | 38.0 | | |
| full range (min-max) | 32.0 to 51.0 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Male | 22 | 220 | |
| Nordwood Hamilton Scale<br>Units: Subjects | | | |
| 03 | 4 | 62 | |
| 03A | 1 | 22 | |
| 03V | 8 | 79 | |
| 04 | 8 | 54 | |
| 04A | 1 | 3 | |
| Smoker status<br>Units: Subjects | | | |
| No smoker | 14 | 149 | |
| Smoker | 8 | 71 | |
| Fitzpatricks Classification<br>Units: Subjects | | | |
| 01 | 0 | 2 | |
| 02 | 6 | 77 | |
| 03 | 13 | 126 | |
| 04 | 3 | 15 | |

## Subject analysis sets

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

Subject analysis set description:

The Full Analysis Set (FAS) is defined as all randomised patients with at least one application of a treatment.

| Reporting group values | Full analysis Set | | |
|---|---|---|---|
| Number of subjects | 220 | | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 220 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |

| | | | |
|---|---|---|---|
| Age continuous<br>Units: years | | | |
| median | 42.0 | | |
| full range (min-max) | 32.0 to 50.0 | | |
| Gender categorical<br>Units: Subjects | | | |
| Male | 220 | | |
| Nordwood Hamilton Scale<br>Units: Subjects | | | |
| 03 | 62 | | |
| 03A | 22 | | |
| 03V | 79 | | |
| 04 | 54 | | |
| 04A | 3 | | |
| Smoker status<br>Units: Subjects | | | |
| No smoker | 149 | | |
| Smoker | 71 | | |
| Fitzpatricks Classification<br>Units: Subjects | | | |
| 01 | 2 | | |
| 02 | 77 | | |
| 03 | 126 | | |
| 04 | 15 | | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | DC120-Placebo of Alostil |
| Reporting group description: - | |
| Reporting group title | DC0120-Alostil |

Reporting group description:

All patients applied for 16 weeks (Day 1 [V2] to Day 110 ± 3 days [V9]) minoxidil 5% ( DC0120) solution and Alostil solution (one product on each side). The study product DC0120, the reference product ALOSTIL® and the corresponding placebos were randomised between 2 contra-lateral zones, the right and left sides of the frontal areas of the scalp using an incomplete block design. For training purposes, the patient applied the products the first day and 2 more days after within the 5 days after the first application at the Investigational Centre (in the morning or at the end of afternoon) under supervision of a trained person different from the investigator.

| | |
|---|---|
| Reporting group title | Alostil-placebo DC120 |
| Reporting group description: - | |
| Reporting group title | placebo DC0120-placebo Alostil |
| Reporting group description: - | |
| Subject analysis set title | Full analysis Set |
| Subject analysis set type | Full analysis |

Subject analysis set description:

The Full Analysis Set (FAS) is defined as all randomised patients with at least one application of a treatment.

### Primary: Change from baselin of non-vellus Target Area Hair Count (TAHC)

| | |
|---|---|
| End point title | Change from baselin of non-vellus Target Area Hair Count (TAHC)[1] |

End point description:

The primary outcome measure was the change from baseline of nonvellus TAHC (number of hairs with diameter > 30 µm/cm²) measured using the PTG method (Trichoscan®) between V2 (baseline) and V10 (Week 16). The global baseline factor is the mean of the nonvellus TAHC at V2 for each minizone.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

The end point was measured between V2 (baseline) and V10 (Week 16).

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 reporting group Placebo DC0120-Placebo Alostil was not taken into account for the primary endopint because of the use of placebo.

| End point values | DC120-Placebo of Alostil | DC0120-Alostil | Alostil-placebo DC120 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 110 | 44 | |
| Units: hairs/cm² | | | | |
| arithmetic mean (standard error) | 21.99 (± 1.97) | 21.99 (± 1.97) | 21.99 (± 1.97) | |

### Statistical analyses

| | |
|---|---|
| **Statistical analysis title** | Primary analysis |
| Comparison groups | DC120-Placebo of Alostil v DC0120-Alostil v Alostil-placebo DC120 |

| | |
|---|---|
| Number of subjects included in analysis | 198 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse event were reported at each visit during the study period (from study enrolment visit to study-end visits.

Adverse event reporting additional description:

At enrolment, any concomitant disease was reported on the CRF.
At each further visit, the occurrence of AEs since the last visit was to be determined by the patient's spontaneous reporting, the investigator's non-leading questioning and his clinical evaluation (vital signs, physical examination and examination of the scalp).

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 18.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | DC0120-Alostil |
| Reporting group description: - | |
| Reporting group title | DC0120-Placebo of Alostil |
| Reporting group description: - | |
| Reporting group title | Alostil-Placebo of DC0120 |
| Reporting group description: - | |
| Reporting group title | Placebo of DC0120-Placebo of Alostil |
| Reporting group description: - | |

| Serious adverse events | DC0120-Alostil | DC0120-Placebo of Alostil | Alostil-Placebo of DC0120 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 110 (1.82%) | 0 / 44 (0.00%) | 0 / 44 (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 | | | |
| Meniscus injury | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (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 |
| Gastrointestinal disorders | | | |
| Gastritis | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (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 |

| **Serious adverse events** | Placebo of DC0120-Placebo of Alostil | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 0.5 %

| **Non-serious adverse events** | DC0120-Alostil | DC0120-Placebo of Alostil | Alostil-Placebo of DC0120 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 36 / 110 (32.73%) | 15 / 44 (34.09%) | 10 / 44 (22.73%) |
| Vascular disorders | | | |
| Diastolic hypertension | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Surgical and medical procedures | | | |
| Dental care | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 2 | 0 | 1 |
| Endodontic procedure | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 1 | 1 |
| Tooth extraction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth repair | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Application site pain | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 2 / 44 (4.55%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Application site acne | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Application site exfoliation | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Application site pruritus | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 0 | 1 |
| Social circumstances | | | |
| Blood donor | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 2 / 110 (1.82%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Blood thyroid stimulating hormone increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental exposure to product | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Excoriation | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Laceration | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 0 | 1 |
| Meniscus injury | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 5 / 110 (4.55%) | 3 / 44 (6.82%) | 1 / 44 (2.27%) |
| occurrences (all) | 6 | 3 | 1 |
| Orthostatic intolerance | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 0 | 1 |
| Vertigo | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye disorders | | | |
| Dry eye | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 1 | 1 |
| Gastritis | | | |
| subjects affected / exposed | 2 / 110 (1.82%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Pruritus | | | |
| subjects affected / exposed | 6 / 110 (5.45%) | 3 / 44 (6.82%) | 0 / 44 (0.00%) |
| occurrences (all) | 6 | 3 | 0 |
| Skin exfoliation | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 3 / 44 (6.82%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 3 | 3 |
| Skin burning sensation | | | |
| subjects affected / exposed | 2 / 110 (1.82%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Eczema | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Erythema | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 1 | 0 | 1 |
| Eczema asteatotic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertrichosis | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain of skin | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Tendonitis | | | |
| subjects affected / exposed | 2 / 110 (1.82%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Myositis | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 13 / 110 (11.82%) | 6 / 44 (13.64%) | 7 / 44 (15.91%) |
| occurrences (all) | 18 | 6 | 7 |
| Oral herpes | | | |
| subjects affected / exposed | 3 / 110 (2.73%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Rash pustular | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 1 | 0 | 1 |
| Cystitis | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 110 (0.91%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metabolism and nutrition disorders | | | |
| Dyslipidaemia | | | |
| subjects affected / exposed | 0 / 110 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| **Non-serious adverse events** | Placebo of DC0120-Placebo of Alostil | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 22 (31.82%) | | |
| Vascular disorders | | | |
| Diastolic hypertension | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Surgical and medical procedures | | | |
| Dental care | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Endodontic procedure | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth extraction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth repair | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| Application site pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Application site acne | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Application site exfoliation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Application site pruritus | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immune system disorders | | | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Social circumstances | | | |
| Blood donor | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cough | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Investigations | | | |
| Blood thyroid stimulating hormone increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Accidental exposure to product | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Excoriation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laceration | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Orthostatic intolerance | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vertigo | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye disorders | | | |
| Dry eye | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dental caries | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Pruritus | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Skin exfoliation | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Skin burning sensation | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema asteatotic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypertrichosis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bursitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myositis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | | |
| occurrences (all) | 4 | | |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash pustular | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cystitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolism and nutrition disorders | | | |
| Dyslipidaemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| occurrences (all) | 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