



## 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 and its subsequent amendments). The study was conducted in agreement with the International Conference on 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 frontotemporal 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 with 1 blue case of treatment for the left side and one red case for the right side

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	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 cm<sup>2</sup>), 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 cm<sup>2</sup>) 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 cm<sup>2</sup>), 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 cm<sup>2</sup>) on the

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

<b>Arm title</b>	DC0120-Alostil
------------------	----------------

Arm description:

All patients applied for 16 weeks (Day 1 [V2] to Day 110  $\pm$  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 cm<sup>2</sup>), 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 cm<sup>2</sup>) 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 cm<sup>2</sup>), 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 cm<sup>2</sup>) on the frontal area of the scalp.

The application side of the 2 study treatments was randomised.

<b>Arm title</b>	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 cm<sup>2</sup>), 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 cm<sup>2</sup>) 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 cm<sup>2</sup>), 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 cm<sup>2</sup>) on the frontal area of the scalp. The application side of the 2 study treatments was randomised.

<b>Arm title</b>	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 cm<sup>2</sup>), 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 cm<sup>2</sup>) 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 cm<sup>2</sup>), 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 cm<sup>2</sup>) on the frontal area of the scalp.

The application side of the 2 study treatments was randomised.

<b>Number of subjects in period 1</b>	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

<b>Number of subjects in period 1</b>	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 $\pm$ 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 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 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 Units: Subjects			
Male	44	110	44
Nordwood Hamilton Scale Units: Subjects			
03	12	36	10
03A	4	10	7
03V	15	40	16
04	13	23	10
04A	0	1	1
Smoker status Units: Subjects			
No smoker	29	73	33
Smoker	15	37	11
Fitzpatrick's Classification 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 Units: Subjects			
Adults (18-64 years)	22	220	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	38.0		
full range (min-max)	32.0 to 51.0	-	
Gender categorical Units: Subjects			
Male	22	220	
Nordwood Hamilton Scale Units: Subjects			
03	4	62	
03A	1	22	
03V	8	79	
04	8	54	
04A	1	3	
Smoker status Units: Subjects			
No smoker	14	149	
Smoker	8	71	
Fitzpatrick's Classification 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 Units: Subjects			
Adults (18-64 years)	220		
From 65-84 years	0		
85 years and over	0		

Age continuous Units: years median full range (min-max)	42.0 32.0 to 50.0		
Gender categorical Units: Subjects			
Male	220		
Nordwood Hamilton Scale Units: Subjects			
03	62		
03A	22		
03V	79		
04	54		
04A	3		
Smoker status Units: Subjects			
No smoker	149		
Smoker	71		
Fitzpatricks Classification 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 $\pm$ 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) <sup>[1]</sup>
End point description: The primary outcome measure was the change from baseline of nonvellus TAHC (number of hairs with diameter > 30 $\mu\text{m}/\text{cm}^2$ ) 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 endpoint 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/cm <sup>2</sup>				
arithmetic mean (standard error)	21.99 ( $\pm$ 1.97)	21.99 ( $\pm$ 1.97)	21.99 ( $\pm$ 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

<b>Serious adverse events</b>	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 %

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

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



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

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

<b>Non-serious adverse events</b>	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 occurrences (all)	0 / 22 (0.00%) 0		
Hypertension			
subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Surgical and medical procedures			
Dental care			
subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Endodontic procedure			
subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Tooth extraction			

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

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

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