



Clinical trial results:

A PHASE IV, OPEN LABEL, PILOT STUDY OF THE TREATMENT OF CHILDREN WITH MODERATE TO SEVERE ATOPIC DERMATITIS (AD) USING LOCOBASE REPAIR® AS AN ADJUNCTIVE TO STANDARD TREATMENT

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2006-006462-42
Trial protocol	GB
Global end of trial date	16 September 2008

Results information

Result version number	v2 (current)
This version publication date	19 May 2016
First version publication date	02 July 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	REP-EC-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00673725
WHO universal trial number (UTN)	-
Other trial identifiers	Acronym: REPAIR

Notes:

Sponsors

Sponsor organisation name	Astellas Pharma Europe B.V.
Sponsor organisation address	P.O. Box 108, Leiderdorp, Netherlands, 2350 AC
Public contact	Clinical Trial Disclosure, Astellas Pharma Europe B.V., Astellas.resultsdisclosure@astellas.com
Scientific contact	Clinical Trial Disclosure, Astellas Pharma Europe B.V., Astellas.resultsdisclosure@astellas.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	16 September 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 September 2008
Global end of trial reached?	Yes
Global end of trial date	16 September 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of Locobase REPAIR® when used in children with moderate to severe atopic dermatitis (AD)

Protection of trial subjects:

This clinical study was written, conducted and reported in accordance with the protocol, ICH GCP Guidelines, and applicable local regulations, including the European Directive 2001/20/EC, on the protection of human rights, and with the ethical principles that have their origin in the Declaration of Helsinki. Astellas ensures that the use and disclosure of protected health information (PHI) obtained during a research study complies with the federal, national and/or regional legislation related to the privacy and protection of personal information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 March 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

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)	2
Children (2-11 years)	38
Adolescents (12-17 years)	9

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects must have continuously used a topical corticosteroid/Topical Calcineurin Inhibitor (TCI) as active treatment for AD, at least 4 weeks prior to screening. Subjects should have met following wash-out criteria prior to screening: Systemic corticosteroids - 2 weeks, Other investigational drugs - 2 weeks, Light Treatments (UVA, UVB) - 4 weeks.

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable, this was an open label study.

Arms

Arm title	Locobase REPAIR® Twice daily
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Arm description:

Locobase REPAIR® cream to be applied twice daily to all areas with active lesions or dry skin either present at day 1 or that emerge during the study.

Arm type	Experimental
Investigational medicinal product name	Locobase
Investigational medicinal product code	
Other name	REPAIR®
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Locobase REPAIR® is a water-in-oil (W/O) cream with a relatively high percentage of Vaseline and some soft paraffin and carnauba wax. To this solid paraffin has been added in the form of nanoparticles (solid particles with a diameter <1000 nm). The skin lipid fraction of the formulation consists of cholesterol, oleic acid, palmitic acid and ceramide-III in relatively high concentrations. There is no active ingredient in Locobase REPAIR®. Locobase REPAIR® cream was to be applied topically twice daily to all areas with active lesions or dry skin either present at day 1 or that emerged during the study.

Number of subjects in period 1	Locobase REPAIR® Twice daily
Started	49
Completed	34
Not completed	15
Withdrawal of consent	3
Lost to follow-up	6
Adverse event (AE)	4
Other (no adult to accompany patient)	2

Baseline characteristics

Reporting groups

Reporting group title	Locobase REPAIR® Twice daily
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Reporting group description:

Locobase REPAIR® cream to be applied twice daily to all areas with active lesions or dry skin either present at day 1 or that emerge during the study.

Reporting group values	Locobase REPAIR® Twice daily	Total	
Number of subjects	49	49	
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	
Age continuous			
Age values are based on the Safety Analysis Population (SAF). The SAF consisted of all enrolled patients who used Locobase REPAIR®.			
Units: years			
arithmetic mean	7		
standard deviation	± 4.1	-	
Gender categorical			
Gender values are based on the SAF.			
Units: Subjects			
Female	20	20	
Male	29	29	

End points

End points reporting groups

Reporting group title	Locobase REPAIR® Twice daily
Reporting group description: Locobase REPAIR® cream to be applied twice daily to all areas with active lesions or dry skin either present at day 1 or that emerge during the study.	
Subject analysis set title	AD Cleared
Subject analysis set type	Full analysis
Subject analysis set description: The study analysis population for this endpoint consisted of the Full Analysis Set (FAS). The FAS consisted of all enrolled patients who used Locobase REPAIR® and had the baseline and a post-baseline Eczema Area and Severity Index (EASI) completed (i.e., the Physician's Assessments of Individual Signs (PAIS) and Affected Area and the Patient's Assessment of Itch (PAI) were completed). Last observation carried forward (LOCF) analysis.	
Subject analysis set title	Excellent Improvement in AD
Subject analysis set type	Full analysis
Subject analysis set description: FAS, LOCF analysis.	
Subject analysis set title	Marked Improvement in AD
Subject analysis set type	Full analysis
Subject analysis set description: FAS, LOCF analysis.	
Subject analysis set title	Moderate Improvement in AD
Subject analysis set type	Full analysis
Subject analysis set description: FAS, LOCF analysis.	
Subject analysis set title	Slight Improvement in AD
Subject analysis set type	Full analysis
Subject analysis set description: FAS, LOCF analysis.	
Subject analysis set title	AD Improvement Not Appreciable
Subject analysis set type	Full analysis
Subject analysis set description: FAS, LOCF analysis.	
Subject analysis set title	AD Worsened
Subject analysis set type	Full analysis
Subject analysis set description: FAS, LOCF analysis.	
Subject analysis set title	Head and Neck Erythema Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Erythema Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Erythema Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Erythema Severe

Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Edema/induration/papulation Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Edema/induration/papulation Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Edema/induration/papulation Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Edema/induration/papulation Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Excoriation Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Excoriation Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Excoriation Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Excoriation Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Oozing/weeping/crusting Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Oozing/weeping/crusting Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Oozing/weeping/crusting Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Oozing/weeping/crusting Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Scaling Absent

Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Scaling Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Scaling Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Scaling Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Lichenification Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Lichenification Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Lichenification Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Head and Neck Lichenification Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Erythema Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Erythema Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Erythema Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Erythema Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Edema/induration/papulation Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Edema/induration/papulation Mild

Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Edema/induration/papulation Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Edema/induration/papulation Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Excoriation Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Excoriation Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Excoriation Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Excoriation Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Oozing/weeping/crusting Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Oozing/weeping/crusting Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Oozing/weeping/crusting Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Oozing/weeping/crusting Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Scaling Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Scaling Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Scaling Moderate

Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Scaling Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Lichenification Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Lichenification Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Lichenification Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Upper Limbs Lichenification Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Erythema Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Erythema Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Erythema Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Erythema Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Edema/induration/papulation Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Edema/induration/papulation Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Edema/induration/papulation Moderate

Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Edema/induration/papulation Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Excoriation Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Excoriation Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Excoriation Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Excoriation Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Oozing/weeping/crusting Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Oozing/weeping/crusting Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Oozing/weeping/crusting Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Oozing/weeping/crusting Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Scaling Absent
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Scaling Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Trunk Scaling Moderate

Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Trunk Scaling Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Trunk Lichenification Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Trunk Lichenification Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Trunk Lichenification Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Trunk Lichenification Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Erythema Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Erythema Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Erythema Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Erythema Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Edema/induration/papulation Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Edema/induration/papulation Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Edema/induration/papulation Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Edema/induration/papulation Severe

Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Excoriation Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Excoriation Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Excoriation Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Excoriation Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Oozing/weeping/crusting Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Oozing/weeping/crusting Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Oozing/weeping/crusting Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Oozing/weeping/crusting Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Scaling Absent
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Scaling Mild
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Scaling Moderate
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Scaling Severe
Subject analysis set type	Full analysis
Subject analysis set description:	
Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Lichenification Absent

Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Lichenification Mild
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Lichenification Moderate
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Lower Limbs Lichenification Severe
Subject analysis set type	Full analysis
Subject analysis set description: Physician's assessment of individual signs.	
Subject analysis set title	Locobase REPAIR® Twice daily Week 3 LOCF
Subject analysis set type	Full analysis
Subject analysis set description: FAS population	
Subject analysis set title	Summary Statistics at Baseline
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	Summary Statistics at Week 3
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	Summary Statistics Week 3 LOCF
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	AD Much Improved
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	AD Improved
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	AD Slightly Improved
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	AD Same
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	AD Slightly Worse
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	AD Worse

Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	AD Much Worse
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	Patients with at least one visit to a GP
Subject analysis set type	Full analysis
Subject analysis set description: FAS population. General Practitioner (GP).	
Subject analysis set title	Patients with at least one outpatient visit to a hospital
Subject analysis set type	Full analysis
Subject analysis set description: FAS population.	
Subject analysis set title	Application site
Subject analysis set type	Safety analysis
Subject analysis set description: Safety Analysis Set (SAF) population. The SAF consisted of all enrolled patients who used Locobase REPAIR®.	
Subject analysis set title	Non-application site
Subject analysis set type	Safety analysis
Subject analysis set description: SAF population.	
Subject analysis set title	Overall Participants with Treatment-Emergent Adverse Events
Subject analysis set type	Safety analysis
Subject analysis set description: SAF population.	

Primary: Change in the modified Eczema Area and Severity Index (mEASI) from baseline to Week 3

End point title	Change in the modified Eczema Area and Severity Index (mEASI) from baseline to Week 3
End point description: The study analysis population for this endpoint consisted of the Full Analysis Set (FAS). The FAS consisted of all enrolled patients who used Locobase REPAIR® and had the baseline and a post-baseline EASI completed (i.e., the Physician's Assessments of Individual Signs (PAIS) and Affected Area and the Patient's Assessment of Itch (PAI) were completed). The mEASI is not an assessment but a score based on the PAIS and affected area and the PAI. The mEASI was calculated by the sponsor at the time of analysis. The modified EASI combined the EASI and the Itch Score (IS). The Investigator completed the Affected Area Scores (AAS) for each body region and the PAIS for signs of AD. $\text{mEASI} (< 7 \text{ years old at baseline}) = \text{EASI} + \text{IS} \times (\text{AAS Head/Neck (H/N)} \times 0.2 + \text{AAS Upper Limbs (UL)} \times 0.2 + \text{AAS Trunk} \times 0.3 + \text{AAS Lower Limbs (LL)} \times 0.3)$ $\text{mEASI} (\geq 7 \text{ years old at baseline}) = \text{EASI} + \text{IS} \times (\text{AAS H/N} \times 0.1 + \text{AAS UL} \times 0.2 + \text{AAS Trunk} \times 0.3 + \text{AAS LL} \times 0.4)$ Highest possible score was: $72 + 18 = 90$.	
End point type	Primary
End point timeframe: Baseline to Week 3.	

End point values	Locobase REPAIR® Twice daily	Locobase REPAIR® Twice daily Week 3 LOCF	Summary Statistics at Baseline	Summary Statistics at Week 3
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30 ^[1]	41 ^[2]	43 ^[3]	30 ^[4]
Units: mEASI (see description)				
arithmetic mean (standard deviation)	-7.77 (± 11.55)	-6.73 (± 10.72)	17.25 (± 12.78)	9.76 (± 8.63)

Notes:

[1] - Change in mEASI from baseline to Week 3.

[2] - Change in mEASI from baseline to Week 3 LOCF. Two patients had a missing mEASI at Week 3.

[3] - Summary Statistics at Baseline.

[4] - Summary Statistics at Week 3.

End point values	Summary Statistics Week 3 LOCF			
Subject group type	Subject analysis set			
Number of subjects analysed	41 ^[5]			
Units: mEASI (see description)				
arithmetic mean (standard deviation)	10.99 (± 10.06)			

Notes:

[5] - Summary Statistics Week 3 LOCF. Two patients had a missing mEASI at Week 3.

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

The hypothesis for the comparison is given as follows:

H0: There is no change in the mEASI at week 3 compared to baseline

H1: There is a change in the mEASI at week 3 compared to baseline

There were actually 30 subjects in this analysis, since the comparison includes the subjects at baseline and week 3.

Comparison groups	Summary Statistics at Baseline v Summary Statistics at Week 3
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other ^[6]
P-value	= 0.0009 ^[7]
Method	t-test, 2-sided

Notes:

[6] - The primary variable was tested by use of a 2-sided paired t-test at a significance level of 5% on patients of the FAS who had a mEASI at week 3.

[7] - Two-sided paired t-test ($\alpha=0.05$)

t-value= -3.69

Statistical analysis title	Statistical analysis 2
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Statistical analysis description:

The hypothesis for the comparison is given as follows:

H0: There is no change in the mEASI at week 3 compared to baseline

H1: There is a change in the mEASI at week 3 compared to baseline

There were actually 41 subjects in this analysis, since the comparison includes the subjects at baseline and week 3 LOCF (Two patients had a missing mEASI at Week 3).

Comparison groups	Summary Statistics at Baseline v Summary Statistics Week 3 LOCF
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other ^[8]
P-value	= 0.0003 ^[9]
Method	t-test, 2-sided

Notes:

[8] - The primary variable was tested by use of a 2-sided paired t-test at a significance level of 5% on patients of the FAS who had a mEASI at week 3 (including data imputed using a LOCF approach). Two patients had a missing mEASI at Week 3.

[9] - Two-sided paired t-test ($\alpha=0.05$)
t-value=-4.02

Secondary: Change in the mEASI from baseline to Day 10 and Week 6

End point title	Change in the mEASI from baseline to Day 10 and Week 6
End point description: The study analysis population for this endpoint consisted of the FAS.	
End point type	Secondary
End point timeframe: Baseline to Day 10 and Week 6.	

End point values	Locobase REPAIR® Twice daily			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: mEASI				
arithmetic mean (standard deviation)				
Day 10 [n=36]	-7.5 (± 9.69)			
Week 6 [n=28]	-7.5 (± 10.88)			
Week 6 LOCF [n=42]	-7.31 (± 10.87)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in the Eczema Area and Severity Index (EASI) from baseline to Day 10, Week 3 and Week 6

End point title	Change in the Eczema Area and Severity Index (EASI) from baseline to Day 10, Week 3 and Week 6
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End point description:

The study analysis population for this endpoint consisted of the FAS. The EASI is not an assessment but a score based on the Physician's Assessment of Individual Signs (for four signs of atopic dermatitis: Erythema, Edema/Induration/Papulation, Excoriation, Lichenification) and the Affected Area Assessment (for each of four defined body regions: Head/Neck, Upper Limbs, Trunk, Lower Limbs).

EASI CALCULATION

TOTAL EASI (<7 years old at baseline) = Head/Neck (Subtotal) x 0.2+ Upper Limbs (Subtotal) x 0.2 + Trunk (Subtotal) x 0.3 + Lower Limbs (Subtotal) x 0.3

TOTAL EASI (≥ 7 years old at baseline) = Head/Neck (Subtotal) x 0.1 + Upper Limbs (Subtotal) x 0.2 + Trunk (Subtotal) x 0.3 + Lower Limbs (Subtotal) x 0.4

End point type	Secondary
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End point timeframe:

Baseline to Day 10, Week 3 and Week 6.

End point values	Locobase REPAIR® Twice daily			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: EASI (see description)				
arithmetic mean (standard deviation)				
Day 10 [n=37]	-4.79 (± 6.65)			
Week 3 [n=30]	-4.88 (± 7.72)			
Week 3 LOCF [n=42]	-4.13 (± 7.13)			
Week 6 [n=30]	-4.09 (± 7.29)			
Week 6 LOCF [n=43]	-4.46 (± 7.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Patient's Assessment of Itch from baseline to Day 10, Week 3 and Week 6

End point title	Change in Patient's Assessment of Itch from baseline to Day 10, Week 3 and Week 6
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End point description:

The study analysis population for this endpoint consisted of the FAS. Itch was assessed by the subject on a 10 cm visual analogue scale (VAS). The distance between the upper end of the scale ("No Itch") and the subject's mark on the scale was measured by the sponsor. The calculation was based on a modified EASI, the distance was categorized to values 0, 1, 2 and 3 as follows:

Itch score measured distance

0 0 - <2.5 cm

1 2.5 - <5 cm

2 5 - <7.5 cm

3 7.5 - 10 cm

Summary statistics for the observed value at each visit, including LOCF, and changes from baseline for the Itch Score (the classified itch assessment in 0, 1, 2 3) were not analyzed.

End point type	Secondary
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End point timeframe:

Baseline to Day 10, Week 3 and Week 6.

End point values	Locobase REPAIR® Twice daily			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: Itch VAS (cm)				
arithmetic mean (standard deviation)				
Day 10 [n=36]	-2.12 (± 2.91)			
Week 3 [n=30]	-2.42 (± 3.17)			
Week 3 LOCF [n=41]	-2.1 (± 3.26)			
Week 6 [n=28]	-2.76 (± 3.28)			
Week 6 LOCF [n=42]	-2.34 (± 3.25)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Physician's Global Evaluation of Clinical Response from baseline to Day 10, Week 3 and Week 6

End point title	Change in Physician's Global Evaluation of Clinical Response from baseline to Day 10, Week 3 and Week 6
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End point description:

The study analysis population for this endpoint consisted of the FAS. The Physician's Global Evaluation of Clinical Response rates the change for all areas affected on the whole body on day 1 compared to defined visits. The physician completed the following at defined visits during the course of the study:

"Consider the patient's atopic dermatitis as a whole, how it looks, how it feels, how others react to it, etc. Since the patient started his/her first treatment with the study substance, do you think the condition is/shows":

% Improvement (Except for residual discolouration)

Cleared: 100

Excellent Improvement: 90-99

Marked Improvement: 75-89

Moderate Improvement: 50-74

Slight Improvement: 30-49

No Appreciable Improvement: 0-29

Worse: < 0

End point type	Secondary
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End point timeframe:

Baseline to Day 10, Week 3 and Week 6.

End point values	AD Cleared	Excellent Improvement in AD	Marked Improvement in AD	Moderate Improvement in AD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Day 10 [n=37]	2.7	5.4	29.7	16.2
Week 3 [n=30]	0	10	23.3	23.3
Week 3 LOCF [n=42]	2.4	7.1	21.4	21.4
Week 6 [n=30]	0	13.3	30	33.3

Week 6 LOCF [n=43]	0	11.6	25.6	27.9
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End point values	Slight Improvement in AD	AD Improvement Not Appreciable	AD Worsened	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	43	43	43	
Units: percentage of participants				
number (not applicable)				
Day 10 [n=37]	24.3	18.9	2.7	
Week 3 [n=30]	20	10	13.3	
Week 3 LOCF [n=42]	19	16.7	11.9	
Week 6 [n=30]	3.3	10	10	
Week 6 LOCF [n=43]	11.6	14	9.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Total Affected Body Surface Area from baseline to Day 10, Week 3 and Week 6

End point title	Change in Total Affected Body Surface Area from baseline to Day 10, Week 3 and Week 6
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End point description:

The study analysis population for this endpoint consisted of the FAS.

Grading Scale: (Physician`s Assessment of Individual Signs)

0 = None

1 = Mild

2 = Moderate

3 = Severe

Sum of Erythema/Induration/Papulation,Excoriation, Lichenification on defined body regions Head/Neck, Upper Limbs, Trunk, Lower Limbs

Affected Area Score:

Score 0 1 2 3 4 5 6

Affected Area (%) 0 1-9 10-29 30-49 50-69 70-89 90-100

4 Subtotal = Sum2 x Affected Area Score (0-6)^3

End point type	Secondary
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End point timeframe:

Baseline to Day 10, Week 3 and Week 6.

End point values	Locobase REPAIR® Twice daily			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: percentage of participants				
arithmetic mean (standard deviation)				
Day 10 [n=37]	-5.49 (± 11.95)			
Week 3 [n=30]	-4.86 (± 14.87)			
Week 3 LOCF [n=42]	-4.13 (± 13.74)			
Week 6 [n=30]	-7.56 (± 16.6)			
Week 6 LOCF [n=43]	-6.88 (± 14.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Assessment of Individual Signs

End point title	Physician's Assessment of Individual Signs
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End point description:

The study analysis population for this endpoint consisted of the FAS.

Grading Scale: (Physician's Assessment of Individual Signs)

0 = None

1 = Mild

2 = Moderate

3 = Severe

Sum of Erythema/Induration/Papulation, Excoriation, Lichenification on defined body regions Head/Neck, Upper Limbs, Trunk, Lower Limbs

Affected Area Score:

Score 0 1 2 3 4 5 6

Affected Area (%) 0 1-9 10-29 30-49 50-69 70-89 90-100

4 Subtotal = Sum2 x Affected Area Score (0-6)^3

End point type	Secondary
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End point timeframe:

Baseline, Day 10, Week 3 and Week 6.

End point values	Head and Neck Erythema Absent	Head and Neck Erythema Mild	Head and Neck Erythema Moderate	Head and Neck Erythema Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	34.9	39.5	23.3	2.3
Day 10 [n=37]	51.4	43.2	5.4	0

Week 3 [n=30]	50	43.3	6.7	0
Week 3 LOCF [n=42]	45.2	45.2	9.5	0
Week 6 [n=30]	60	36.7	3.3	0
Week 6 LOCF [n=43]	53.5	37.2	9.3	0

End point values	Head and Neck Edema/induration/papulation Absent	Head and Neck Edema/induration/papulation Mild	Head and Neck Edema/induration/papulation Moderate	Head and Neck Edema/induration/papulation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	51.2	37.2	11.6	0
Day 10 [n=37]	75.7	24.3	0	0
Week 3 [n=30]	70	26.7	3.3	0
Week 3 LOCF [n=42]	71.4	26.2	2.4	0
Week 6 [n=30]	80	20	0	0
Week 6 LOCF [n=43]	74.4	23.3	2.3	0

End point values	Head and Neck Excoriation Absent	Head and Neck Excoriation Mild	Head and Neck Excoriation Moderate	Head and Neck Excoriation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	60.5	27.9	11.6	0
Day 10 [n=37]	83.8	16.2	0	0
Week 3 [n=30]	76.7	20	3.3	0
Week 3 LOCF [n=42]	78.6	19	2.4	0
Week 6 [n=30]	83.3	16.7	0	0
Week 6 LOCF [n=43]	76.7	20.9	2.3	0

End point values	Head and Neck Oozing/weeping/crusting Absent	Head and Neck Oozing/weeping/crusting Mild	Head and Neck Oozing/weeping/crusting Moderate	Head and Neck Oozing/weeping/crusting Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	86	9.3	4.7	0
Day 10 [n=37]	94.6	5.4	0	0
Week 3 [n=30]	100	0	0	0
Week 3 LOCF [n=42]	97.6	2.4	0	0

Week 6 [n=30]	100	0	0	0
Week 6 LOCF [n=43]	97.7	2.3	0	0

End point values	Head and Neck Scaling Absent	Head and Neck Scaling Mild	Head and Neck Scaling Moderate	Head and Neck Scaling Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	60.5	39.5	0	0
Day 10 [n=37]	75.7	24.3	0	0
Week 3 [n=30]	73.3	26.7	0	0
Week 3 LOCF [n=42]	69	31	0	0
Week 6 [n=30]	90	10	0	0
Week 6 LOCF [n=43]	79.1	20.9	0	0

End point values	Head and Neck Lichenification Absent	Head and Neck Lichenification Mild	Head and Neck Lichenification Moderate	Head and Neck Lichenification Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	74.4	25.6	0	0
Day 10 [n=37]	81.1	18.9	0	0
Week 3 [n=30]	90	10	0	0
Week 3 LOCF [n=42]	85.7	14.3	0	0
Week 6 [n=30]	90	10	0	0
Week 6 LOCF [n=43]	88.4	11.6	0	0

End point values	Upper Limbs Erythema Absent	Upper Limbs Erythema Mild	Upper Limbs Erythema Moderate	Upper Limbs Erythema Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	2.3	41.9	48.8	7
Day 10 [n=37]	8.1	62.2	29.7	0
Week 3 [n=30]	0	76.7	20	3.3
Week 3 LOCF [n=42]	2.4	71.4	23.8	2.4
Week 6 [n=30]	20	56.7	20	3.3
Week 6 LOCF [n=43]	14	60.5	20.9	4.7

End point values	Upper Limbs Edema/induration/ papulation Absent	Upper Limbs Edema/induration/ papulation Mild	Upper Limbs Edema/induration/ papulation Moderate	Upper Limbs Edema/induration/ papulation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	9.3	46.5	39.5	4.7
Day 10 [n=37]	27	67.6	5.4	0
Week 3 [n=30]	30	53.3	16.7	0
Week 3 LOCF [n=42]	35.7	50	14.3	0
Week 6 [n=30]	46.7	36.7	13.3	3.3
Week 6 LOCF [n=43]	39.5	46.5	11.6	2.3

End point values	Upper Limbs Excoriation Absent	Upper Limbs Excoriation Mild	Upper Limbs Excoriation Moderate	Upper Limbs Excoriation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	7	46.5	39.5	7
Day 10 [n=37]	13.5	64.9	21.6	0
Week 3 [n=30]	26.7	53.3	20	0
Week 3 LOCF [n=42]	26.2	52.4	21.4	0
Week 6 [n=30]	23.3	53.3	23.3	0
Week 6 LOCF [n=43]	23.3	51.2	25.6	0

End point values	Upper Limbs Oozing/weeping/ crusting Absent	Upper Limbs Oozing/weeping/ crusting Mild	Upper Limbs Oozing/weeping/ crusting Moderate	Upper Limbs Oozing/weeping/ crusting Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	55.8	32.6	11.6	0
Day 10 [n=37]	73	24.3	2.7	0
Week 3 [n=30]	80	20	0	0
Week 3 LOCF [n=42]	83.3	14.3	2.4	0
Week 6 [n=30]	80	20	0	0
Week 6 LOCF [n=43]	81.4	16.3	2.3	0

End point values	Upper Limbs Scaling Absent	Upper Limbs Scaling Mild	Upper Limbs Scaling Moderate	Upper Limbs Scaling Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	30.2	55.8	14	0
Day 10 [n=37]	45.9	51.4	2.7	0
Week 3 [n=30]	46.7	50	3.3	0
Week 3 LOCF [n=42]	45.2	52.4	2.4	0
Week 6 [n=30]	56.7	43.3	0	0
Week 6 LOCF [n=43]	46.5	51.2	2.3	0

End point values	Upper Limbs Lichenification Absent	Upper Limbs Lichenification Mild	Upper Limbs Lichenification Moderate	Upper Limbs Lichenification Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	23.3	55.8	20.9	0
Day 10 [n=37]	40.5	51.4	8.1	0
Week 3 [n=30]	43.3	56.7	0	0
Week 3 LOCF [n=42]	40.5	52.4	7.1	0
Week 6 [n=30]	43.3	50	6.7	0
Week 6 LOCF [n=43]	41.9	51.2	7	0

End point values	Trunk Erythema Absent	Trunk Erythema Mild	Trunk Erythema Moderate	Trunk Erythema Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	34.9	53.5	11.6	0
Day 10 [n=37]	56.8	35.1	8.1	0
Week 3 [n=30]	60	30	10	0
Week 3 LOCF [n=42]	54.8	35.7	9.5	0
Week 6 [n=30]	63.3	30	6.7	0
Week 6 LOCF [n=43]	53.5	37.2	9.3	0

End point values	Trunk Edema/induration/papulation Absent	Trunk Edema/induration/papulation Mild	Trunk Edema/induration/papulation Moderate	Trunk Edema/induration/papulation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	62.8	30.2	7	0
Day 10 [n=37]	78.4	21.6	0	0
Week 3 [n=30]	73.3	20	6.7	0
Week 3 LOCF [n=42]	71.4	23.8	4.8	0
Week 6 [n=30]	80	16.7	3.3	0
Week 6 LOCF [n=43]	76.7	16.3	7	0

End point values	Trunk Excoriation Absent	Trunk Excoriation Mild	Trunk Excoriation Moderate	Trunk Excoriation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	65.1	20.9	9.3	4.7
Day 10 [n=37]	73	27	0	0
Week 3 [n=30]	70	23.3	6.7	0
Week 3 LOCF [n=42]	69	26.2	4.8	0
Week 6 [n=30]	73.3	23.3	3.3	0
Week 6 LOCF [n=43]	69.8	23.3	7	0

End point values	Trunk Oozing/weeping/crusting Absent	Trunk Oozing/weeping/crusting Mild	Trunk Oozing/weeping/crusting Moderate	Trunk Oozing/weeping/crusting Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	86	9.3	4.7	0
Day 10 [n=37]	91.9	8.1	0	0
Week 3 [n=30]	93.3	6.7	0	0
Week 3 LOCF [n=42]	92.9	7.1	0	0
Week 6 [n=30]	93.3	6.7	0	0
Week 6 LOCF [n=43]	93	7	0	0

End point values	Trunk Scaling Absent	Trunk Scaling Mild	Trunk Scaling Moderate	Trunk Scaling Severe
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Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	60.5	39.5	0	0
Day 10 [n=37]	78.4	21.6	0	0
Week 3 [n=30]	90	10	0	0
Week 3 LOCF [n=42]	83.3	16.7	0	0
Week 6 [n=30]	86.7	13.3	0	0
Week 6 LOCF [n=43]	81.4	18.6	0	0

End point values	Trunk Lichenification Absent	Trunk Lichenification Mild	Trunk Lichenification Moderate	Trunk Lichenification Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	72.1	25.6	2.3	0
Day 10 [n=37]	81.1	18.9	0	0
Week 3 [n=30]	80.8	20	0	0
Week 3 LOCF [n=42]	78.6	21.4	0	0
Week 6 [n=30]	80	16.7	3.3	0
Week 6 LOCF [n=43]	81.4	16.3	2.3	0

End point values	Lower Limbs Erythema Absent	Lower Limbs Erythema Mild	Lower Limbs Erythema Moderate	Lower Limbs Erythema Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	4.7	23.3	55.8	16.3
Day 10 [n=37]	8.1	56.8	35.1	0
Week 3 [n=30]	3.3	46.7	43.3	6.7
Week 3 LOCF [n=42]	4.8	42.9	47.6	4.8
Week 6 [n=30]	10	46.7	33.3	10
Week 6 LOCF [n=43]	7	44.2	39.5	9.3

End point values	Lower Limbs Edema/induration/papulation Absent	Lower Limbs Edema/induration/papulation Mild	Lower Limbs Edema/induration/papulation Moderate	Lower Limbs Edema/induration/papulation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				

number (not applicable)				
Baseline [n=43]	14	30.2	48.8	7
Day 10 [n=37]	21.6	56.8	18.9	2.7
Week 3 [n=30]	23.3	43.3	33.3	0
Week 3 LOCF [n=42]	23.8	38.1	35.7	2.4
Week 6 [n=30]	33.3	40	16.7	10
Week 6 LOCF [n=43]	25.6	39.5	27.9	7

End point values	Lower Limbs Excoriation Absent	Lower Limbs Excoriation Mild	Lower Limbs Excoriation Moderate	Lower Limbs Excoriation Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	14	27.9	48.8	9.3
Day 10 [n=37]	13.5	70.3	16.2	0
Week 3 [n=30]	26.7	46.7	23.3	3.3
Week 3 LOCF [n=42]	23.8	45.2	28.6	2.4
Week 6 [n=30]	20	53.3	20	6.7
Week 6 LOCF [n=43]	20.9	48.8	23.3	7

End point values	Lower Limbs Oozing/weepin g/crusting Absent	Lower Limbs Oozing/weepin g/crusting Mild	Lower Limbs Oozing/weepin g/crusting Moderate	Lower Limbs Oozing/weepin g/crusting Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	53.5	34.9	11.6	0
Day 10 [n=37]	78.4	21.6	0	0
Week 3 [n=30]	66.7	26.7	6.7	0
Week 3 LOCF [n=42]	71.4	23.8	4.8	0
Week 6 [n=30]	70	23.3	6.7	0
Week 6 LOCF [n=43]	74.4	20.9	4.7	0

End point values	Lower Limbs Scaling Absent	Lower Limbs Scaling Mild	Lower Limbs Scaling Moderate	Lower Limbs Scaling Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	23.3	60.5	16.3	0
Day 10 [n=37]	40.5	51.4	8.1	0

Week 3 [n=30]	40	53.3	6.7	0
Week 3 LOCF [n=42]	42.9	50	7.1	0
Week 6 [n=30]	56.7	33.3	10	0
Week 6 LOCF [n=43]	48.8	39.5	11.5	0

End point values	Lower Limbs Lichenification Absent	Lower Limbs Lichenification Mild	Lower Limbs Lichenification Moderate	Lower Limbs Lichenification Severe
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Baseline [n=43]	30.2	48.8	18.6	2.3
Day 10 [n=37]	40.5	43.2	16.2	0
Week 3 [n=30]	40	53.3	6.7	0
Week 3 LOCF [n=42]	35.7	50	14.3	0
Week 6 [n=30]	40	43.3	16.7	0
Week 6 LOCF [n=43]	39.5	41.9	18.6	0

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's/Guardian's/Parent(s) Assessment of Global Response

End point title	Patient's/Guardian's/Parent(s) Assessment of Global Response
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End point description:

The study analysis population for this endpoint consisted of the FAS. Patient's/Guardian's/Parent(s) Assessment of Global Response: The patient/guardian/parent(s) was instructed to answer the following questions at day 10, week 3 & week 6 (visits 3-5). "Consider your atopic dermatitis as a whole, how it looks, how it feels, how others react to it etc. Since the time you started treatment with the study substance, do you think the condition is":

Much Improved
Improved
Slightly Improved
Same
Slightly Worse
Worse
Much Worse

End point type	Secondary
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End point timeframe:

Day 10, Week 3 and Week 6.

End point values	AD Much Improved	AD Improved	AD Slightly Improved	AD Same
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	43	43
Units: percentage of participants				
number (not applicable)				
Day 10 [n=36]	36.1	19.4	27.8	11.1
Week 3 [n=30]	33.3	23.3	13.3	10
Week 3 LOCF [n=41]	34.1	19.5	17.1	9.8
Week 6 [n=28]	39.3	28.6	3.6	17.9
Week 6 LOCF [n=42]	33.3	31	4.8	16.7

End point values	AD Slightly Worse	AD Worse	AD Much Worse	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	43	43	43	
Units: percentage of participants				
number (not applicable)				
Day 10 [n=36]	2.8	0	2.8	
Week 3 [n=30]	16.7	0	3.3	
Week 3 LOCF [n=41]	14.6	0	4.9	
Week 6 [n=28]	7.1	3.6	0	
Week 6 LOCF [n=42]	9.5	2.4	2.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Euroqol 5 Dimensions Questionnaire (EQ-5D) from baseline to Week 6

End point title	Change in Euroqol 5 Dimensions Questionnaire (EQ-5D) from baseline to Week 6
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End point description:

The study analysis population for this endpoint consisted of the FAS. The EQ-5D comprises five dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and each dimension comprises three levels (1=no problems, 2=some/moderate problems, 3=extreme problems). The EQ-5D VAS records the respondents-rated health status on a vertical graduated VAS ranging from 0 indicating the worst imaginable state to 100 indicating the best imaginable state of the patient's health. EQ-5D questionnaire was used to calculate the utility of an individual patient and produces a utility value of between 0 (death) and 1 (perfect health). The EQ-5D was not completed for children less than 3 years of age.

End point type	Secondary
End point timeframe:	
Baseline to Week 6.	

End point values	Locobase REPAIR® Twice daily			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: EQ-5D VAS and Utility Scores				
arithmetic mean (standard deviation)				
EQ-5D VAS	7.7 (± 12.2)			
EQ-5D Utility Score TTO UK	0.13 (± 0.24)			
EQ-5D Utility Score VAS UK	0.13 (± 0.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Children's Dermatology Life Quality Index (CDLQI)] from baseline to Week 6

End point title	Change in Children's Dermatology Life Quality Index (CDLQI)] from baseline to Week 6
End point description:	
The study analysis population for this endpoint consisted of the FAS. The CDLQI consists of 10 questions and was completed by the patients themselves with help from their parent(s)/guardian where necessary. The CDLQI was calculated by summing the score of each question resulting in a total score between 0 and 30. Furthermore, six subscores were calculated. The higher the score, the more QoL is impaired. Children under 5 years of age were not asked to complete the CDLQI.	
End point type	Secondary
End point timeframe:	
Baseline to Week 6.	

End point values	Locobase REPAIR® Twice daily			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: CDLQI Scores				
arithmetic mean (standard deviation)				
CDLQI Total Score [n=16]	-5.1 (± 6.5)			
CDLQI Subscore Symptoms and Feelings [n=17]	-1.6 (± 1.6)			
CDLQI Subscore Leisure [n=17]	-1.2 (± 2.2)			
CDLQI Subscore School and Holiday [n=3]	-0.7 (± 1.2)			
CDLQI Subscore Personal Relationship [n=16]	-0.4 (± 1.7)			
CDLQI Subscore Sleep [n=15]	-0.7 (± 1)			
CDLQI Subscore Treatment [n=16]	-0.6 (± 0.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Resource Utilization Questionnaire

End point title	Resource Utilization Questionnaire
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End point description:

The study analysis population for this endpoint consisted of the FAS. The Resource Utilization Questionnaire was used to record the patients' visits to a general practitioner (GP) for AD, the patients' hospital outpatient visits and the patients' admissions due to AD during the study. Patients completed a resource utilization questionnaire at all visits.

End point type	Secondary
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End point timeframe:

Baseline, Day 10, Week 3 and Week 6.

End point values	Patients with at least one visit to a GP	Patients with at least one outpatient visit to a hospital		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	43		
Units: percentage of participants				
number (not applicable)				
Up to 91 days before Baseline - ≥ Baseline [n=43]	41.9	9.3		
> Baseline - ≤ Day 10 [n=43]	16.3	4.7		
> Baseline - ≤ Week 3 [n=43]	16.3	4.7		
> Baseline - ≤ Week 6 [n=43]	16.3	4.7		
> Day 10 - ≤ Week 3 [n=30]	3.3	3.3		
> Week 3 - ≤ Week 6 [n=31]	3.2	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Safety as assessed by recording adverse events, and laboratory assessments

End point title	Safety as assessed by recording adverse events, and laboratory assessments
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End point description:

The study analysis population for this endpoint consisted of the Safety analysis set (SAF). The SAF consisted of all enrolled patients who used Locobase REPAIR®. Treatment emergent adverse events (TEAE) were those events that commenced on the day or after the first day that study medication was dispensed, unless indicated by the investigator as before first application of study drug.

End point type	Secondary
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End point timeframe:

Up to Week 6.

End point values	Application site	Non-application site	Overall Participants with Treatment-Emergent Adverse Events	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	49	49	49	
Units: Participants				
Total TEAEs	8	10	16	
Serious Adverse Events (SAEs)	0	1	1	
Deaths	0	0	0	
Discontinued due to AEs	3	2	4	
TEAEs Mild	4	5	8	
TEAEs Moderate	4	4	7	
TEAEs Severe	0	1	1	
Treatment related AEs	4	0	4	
Total treatment-related AEs	8	0	8	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

TEAEs were those events that commenced on the day or after the first day that study medication was dispensed, unless indicated by the investigator as before first application of study drug.

Adverse event reporting additional description:

An adverse event was defined as any untoward medical occurrence in a patient entered into the study, which did not necessarily have a causal relationship with the treatment. The study analysis population for this endpoint consisted of the SAF.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1.10
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Reporting groups

Reporting group title	Locobase REPAIR® Twice daily
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Reporting group description:

Locobase REPAIR® cream to be applied twice daily to all areas with active lesions or dry skin either present at day 1 or that emerge during the study.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There were no non-serious adverse events within the 5% or more frequency threshold for reporting non-serious adverse events.

Serious adverse events	Locobase REPAIR® Twice daily		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 49 (2.04%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 49 (2.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Locobase REPAIR® Twice daily		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)		

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