Benefits of an Anti-Relapse Gel-Cream Intended for Very Dry, Irritated to Atopic Sensitive Skin: Results From Clinical Study in Babies, Children and Teenagers in India and Argentina

P0131

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INTRODUCTION

Atopic Dermatitis (AD) is a chronic, relapsing inflammatory dermatosis related to an altered skin barrier, characterized by eczematous flares, xerosis, and pruritus. Affecting 10 – 25 % of children in industrialized countries,[1] it significantly impairs family quality of life, thereby justifying the integration of adapted dermocosmetic strategies providing intensive **anti-pruritic and lipid-replenishing effects**. The objective of this clinical study was to evaluate the **effectiveness** and **tolerance** of an emollient with active ingredients in a **light gel-cream texture** to prevent recurrent acute flares of eczema in patients with AD in **warm and humid environments**.

MATERIALS & METHODS

This **intra-individual** and prospective study was conducted in **Argentina** and **India** under **dermatological control**. 46 subjects (4 subjects *lost to follow-up*) were included, aged 6 months to 15 years, with **moderate AD and active eruptions**. Subjects received topical treatment (corticosteroids) at inclusion (D0) and had to apply the investigational light gel-cream over their entire body for **120 days**, using standardized "3-6-9" method, adjusted for age and body surface area. Several assessments were performed at baseline (D0) and during follow-up visits (D30, D60, D120) including:

Clinical assessment
- Eczema Area and Severity Index (EASI)
- Investigator Global Assessment (IGA)
- Relapses

Biometrological assessment
- Stratum Corneum (SC) Hydration
- Transepidermal water loss (TEWL)

Subjective Assessments
- Itching, Insomnia
- Quality of Life
- Efficacy

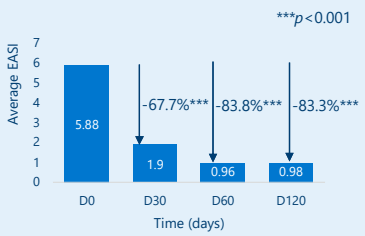
Dermatological Tolerance

RESULTS

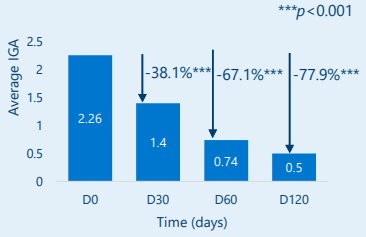
Clinical assessment

After 120 days of study product application (with 10.5 days of topical corticosteroids treatment in average at the beginning), **IGA** showed a significant improvement in **AD severity**. The mean **EASI** decreased by **-83.3%** (D120 vs. D0, $p<0.001$, Wilcoxon signed rank-test) and **IGA** decreased by **-77.9%** (D120 vs. D0, $p<0.001$, Wilcoxon signed rank-test):

Graph 1: Evolution of EASI



Graph 2: Evolution of IGA

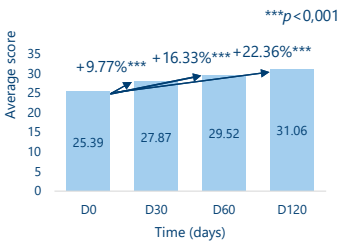


The mean **number of relapses** was also reduced by **-89.2%** (p<0.001, Wilcoxon signed rank-test) comparing the 4 months of the study with the four months prior to it.

Biometrological assessment

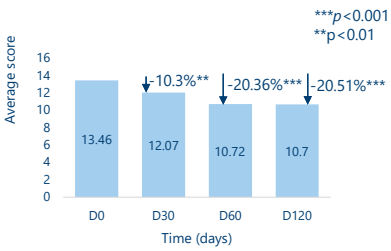
(realized outside flare-up areas)

Graph 3: Evolution of SC Hydration



Stratum Corneum Hydration
Increase of **22.36%** (D120 vs. D0, $p<0.001$, Wilcoxon signed rank-test)

Graph 4: Evolution of TEWL



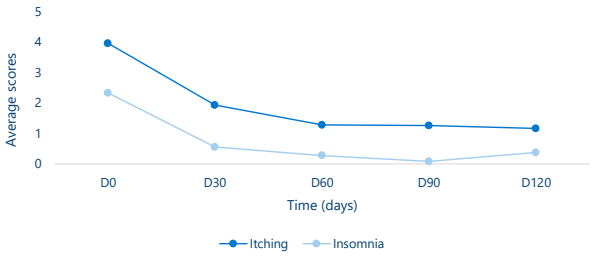
Transepidermal Water Loss
Decrease of **-20.51%** (D120 vs. D0, $p<0.001$, Wilcoxon signed rank-test)

Dermatological tolerance

The product was **very well tolerated** by the subjects with no adverse event reported.

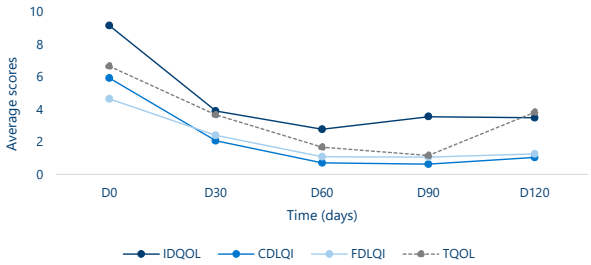
Subjective Assessments

Graph 5: Evolution of Itching and Insomnia scores



Patient-reported outcomes also improved significantly, with a **-70.5%** reduction in **Itching** score and an **-83.6%** reduction in **Insomnia** score (D120 vs. D0, $p<0.001$, Wilcoxon signed rank-test).

Graph 6: Evolution of Quality of Life



Quality of life scores decreased significantly:
- For **infants**, regarding the Infants' Dermatitis Quality of Life Index (**IDQOL**) reduction of **-61.9%**, D120 vs. D0 ($p<0.05$, Wilcoxon signed rank-test)
- For **children**, regarding the Children's Dermatitis Life Quality Index (**CDLQI**) reduction of **-82.5%**, D120 vs. D0 ($p<0.001$, Wilcoxon signed rank-test)
- For **families**, regarding the Family Dermatology Life Quality Index (**FDLQI**) reduction of **-72.9%**, D120 vs. D0 ($p<0.001$, Wilcoxon signed rank-test)

As for **teenagers**, the changes concerning the Teenager' Quality of Life (**TQOL**) were considered as not significant, likely due to a small sample size.

Subjective efficacy

The product effectiveness was rated very positively, with between **97.6% to 100%** of the subjects reporting benefits across all evaluated parameters.

CONCLUSION

This study indicates that the investigational gel-cream texture emollient is **very well tolerated** and is **clinically effective in alleviating AD signs** among **infants, children and teenagers**, in hot and humid regions. Notable improvements were observed across clinical indicators, patient-reported symptoms, skin barrier integrity, and overall quality of life, along with a marked decrease in relapse frequency. The product's favorable tolerability profile and its high satisfaction rates suggest its appropriateness for daily application in **warm environments**, supporting its position as a reliable option for sustained AD management.

[1]Bylund, S.; von Kobyletzki, L. B.; Svalstedt, M.; Svensson, Å. Prevalence and Incidence of Atopic Dermatitis: A Systematic Review. *Acta Derm.-Venereol.* **2020**, *100*, 320–329

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