

# Novel anti-inflammatory emollient gel: assessment of efficacy in SLS provoked/irritated skin

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## Introduction:

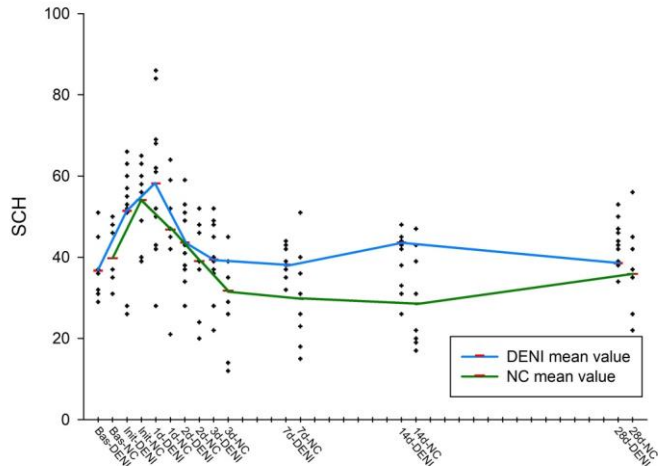
- Adex gel (DENI gel) is a novel leave-on emollient, containing an anti-inflammatory substance, nicotinamide, for use in the treatment and management of dry skin conditions prone to inflammation, including eczema and psoriasis. The aim of the study was to evaluate the effects of DENI gel on skin hydration and barrier function on provoked/irritated skin over a period of 28 days.

## Clinical study design:

- Randomised, investigator-blind study in 8 volunteers. Two test sites (9 cm<sup>2</sup>) on the volar aspects of both forearms were artificially irritated by pre-treatment with SLS.
- The irritated sites on one arm were treated with DENI gel, four times daily for 28 days. The irritated sites on the other arm were left as **non-treated controls (NC)**.

## Measurements:

- Triplicate stratum corneum hydration (SCH) (Corneometer® CM 825)
- Transepidermal water loss (TEWL) (Tewameter® TM 210)
- Basal values** measured prior to inducing skin irritation on Day -1.
- Initial values** measured 24 hours after inducing skin irritation on Day 0 before the first DENI gel application
- All measurements also performed on Days 1, 2, 3, 7, 14 and 28.



When applied to dry and irritated skin Adex gel (DENI gel):

- achieved significant improvement in skin barrier function within 7 days (as opposed to within 14 days if no treatment was used)
- provided effective skin hydration.

Figure 1. Mean stratum corneum hydration values for all treated (DENI gel) and non-treated (NC) sites

## Results:

- There were no differences in basal or initial values between treated and non-treated sites. Six volunteers completed the study. Comparisons were performed in two ways: by comparing the basal measurements with values obtained at each time point following treatment with DENI gel; and by comparing NC values (at irritated sites) with corresponding DENI treatment sites at each time point. Statistical significances for all pairwise comparisons were tested using two-way ANOVA and post hoc Bonferroni t-testing where appropriate.
- As expected with SLS induced skin dryness and irritation, SCH and TEWL values were significantly increased on Day 0 in comparison to the basal values.
- For NC sites, SCH values were significantly lower (drier) than basal values on Days 7 and 14 and returned to normal basal values by Day 28 (Figure 1). **Irritated sites treated with DENI gel had statistically significantly higher SCH values in comparison to NC irritated sites on Days 1, 7, 14 and 28.**
- For NC irritated sites, TEWL values compared to basal were significantly increased initially (impaired barrier function) and remained so on Days 1, 2, 3 and 7, and did not return to normal basal levels until Day 14 (Figure 2). **Irritated sites treated with DENI gel had significantly higher TEWL values compared to basal on Days 1, 2 and 3 only, returning to normal values by Day 7 and thereafter.**

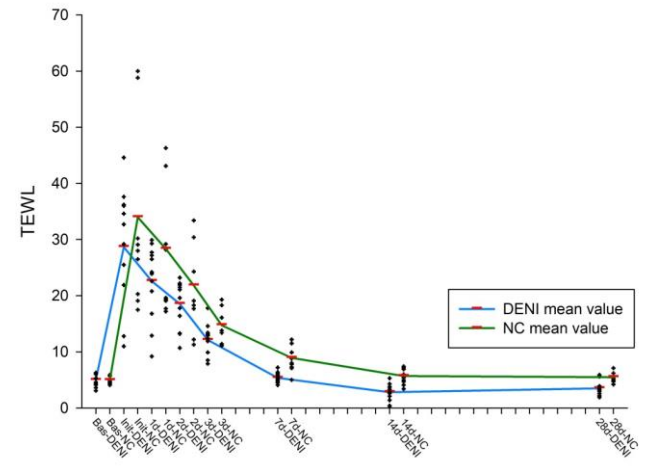


Figure 2. Mean transepidermal water loss values for all treated (DENI gel) and non-treated (NC) sites