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Evaluation of an Emollient with Nicotinamide in Managing Moderate Atopic Eczema in Paediatric Patients: A Real-World GP Study

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Introduction

Adex® Gel (DENI) is an emollient that contains the ancillary anti-inflammatory agent nicotinamide, potentially offering an alternative therapeutic option to conventional emollients, topical corticosteroids and topical calcineurin inhibitors. This study evaluates its efficacy in the treatment of moderate atopic eczema in children, in real-world clinical settings.

Methodology

This was a prospective, open-label study conducted in 11 GP centres across the UK, involving 60 screened children (aged 1 year to 15 years) with moderate atopic eczema. DENI was used three times daily for 4 weeks instead of their usual emollient or as the first-line treatment for moderate atopic eczema, in both scenarios, without supplementary use of topical (or oral) corticosteroids or immunomodulators (topical calcineurin inhibitors). The clinical endpoints were the change from baseline in SCORing for Atopic Dermatitis (SCORAD)* measurements after 2 and 4 weeks of treatment, including individual symptom components.

Results

The mean disease severity score (SCORAD) improved significantly from 37.14 (moderate atopic eczema) at baseline, to 22.56 (mild atopic eczema) after 2 weeks and to 18.48 (mild atopic eczema) after 4 weeks, in the per protocol (PP) analysis. The improvements were statistically significant at both week 2 and week 4 (p<0.0001, n=41) and achieved MCID*.

Improvements were also noted in individual SCORAD components. The number of clinical signs rated as moderate or severe (redness, swelling, dryness, oozing/crusting, lichenification, and excoriation) decreased after 4 weeks and statistical significances were observed for parameters that were statistically analysed (redness, swelling and dryness). Additionally, improvements in subjective symptoms of itch and sleeplessness were recorded, with a mean improvement of 3.0 (52.4%) in itch intensity scores (p<0.0001) and 2.3 (37.8%) in sleeplessness intensity scores over 4 weeks. Related adverse events were reported, with stinging, itching, redness and worsening of the eczema symptoms being the most common, but these are expected adverse events when using emollients in children with moderate eczema.

Conclusion

DENI gel demonstrated significant improvements in total SCORAD scores with a significant reduction in individual symptom severity (redness, swelling, dryness, itch, and sleeplessness), and reductions in the percentage of skin area affected. These findings support its role as an effective treatment option for paediatric moderate atopic eczema in primary and secondary care settings and may help reduce reliance on topical corticosteroids.

Figure 1 – Total Percentage Eczema Area Affected – PP Analysis

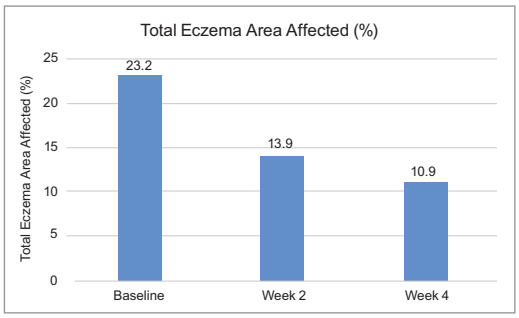
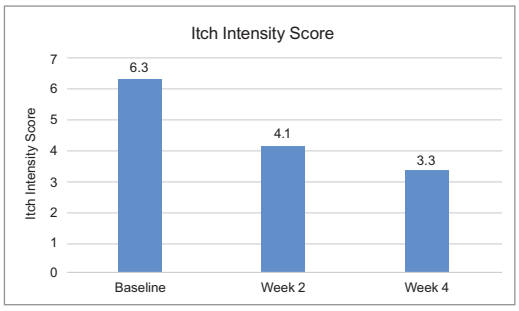


Figure 2 – Itch and Sleeplessness Intensity Scores – PP Analysis



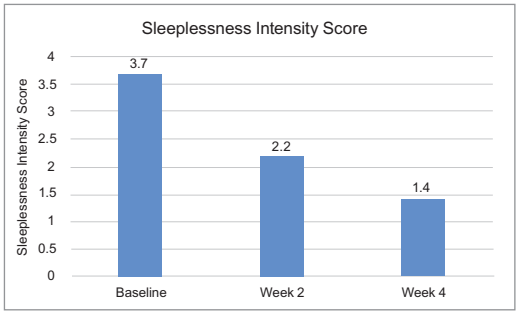
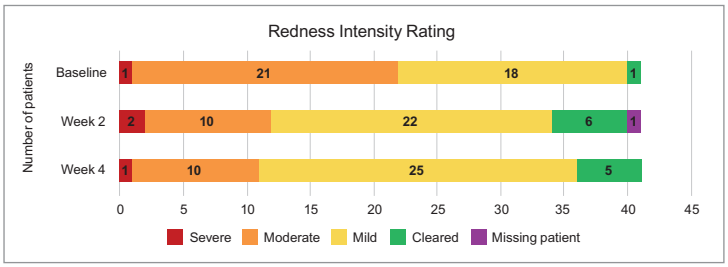
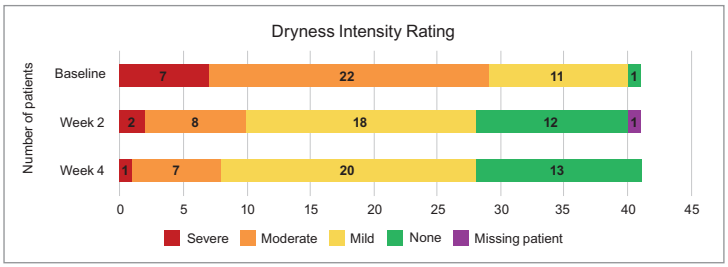


Figure 3 – Redness and Dryness Intensity Scores – PP Analysis





*SCORAD is a tool used in clinical trials to assess atopic dermatitis severity based on disease area, intensity and subjective symptoms (itch and sleeplessness). SCORAD-Index = Mild 0-24; Moderate 25-50; Severe 51-100 (Willemsen, M.G., *et al.*, Determining the severity of atopic dermatitis in children presenting in general practice: an easy and fast method. *Dermatol Res Pract,* ***2009:*** *357046*). Improved SCORAD outcomes of within-patient change of 8.7 is considered the Minimal Clinically Important Difference (MCID) or above.

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