

Open-label evaluation of a novel anti-inflammatory emollient gel in eczema and psoriasis

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Introduction

Adex[®] Gel (DENI) is a novel leave-on emollient, also containing an ancillary anti-inflammatory medicinal substance, nicotinamide, for use in the treatment and management of dry skin conditions prone to inflammation, including eczema and psoriasis. Here we report two studies undertaken to obtain patients' and a medical investigator's feedback on the clinical performance and acceptability of the product, and to assess the product's potential for reducing patients' reliance on topical corticosteroids and immunomodulators.

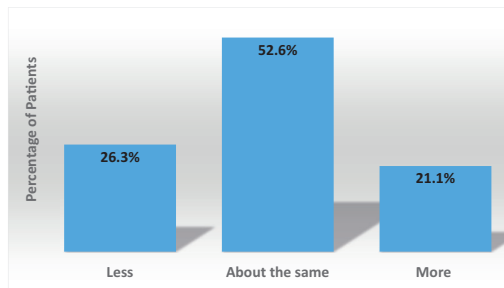
Study design

In the first study, 43 patients accustomed to using emollients in eczema and psoriasis used the new product on its own, or as adjunctive therapy, for two weeks instead of their usual emollient, applying it three times daily or more often if necessary. Using a questionnaire, subjects then indicated whether they 'disagreed strongly', 'disagreed', 'neither disagreed nor agreed', 'agreed' or 'strongly agreed' with various statements about the clinical performance and acceptability of the product.

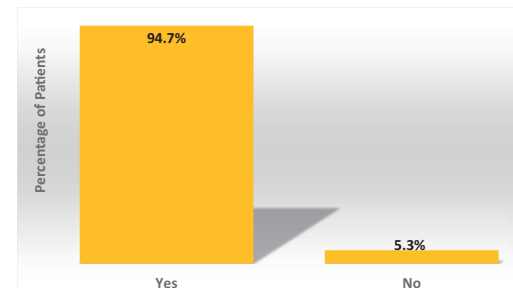
In the second study, nineteen patients used the product again for four weeks, this time using it in whichever way suited them best, and in accordance with the Package Leaflet. Patients then completed a questionnaire to indicate, *inter alia*, how they used it and whether their use of topical corticosteroids and/or immunomodulator treatments was 'less', 'about the same' or 'more' than usual. Patients and the medical investigator also rated various aspects of the performance and acceptability of the treatment.

Results

In both studies, roughly half the patients used DENI Gel to treat psoriasis, the remainder treated various forms of eczema. In the first study, patients responses were very positive, ranging from 81% to 100% agreement with each performance statement (Table 1).



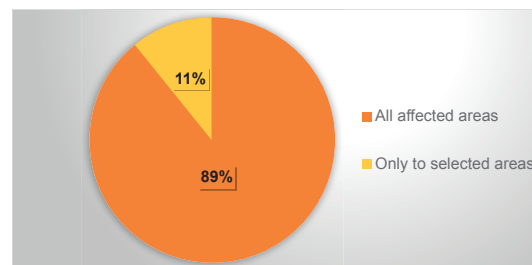
Q1: Thinking about your skin condition and the effectiveness of treatment over the last four weeks, did you need to use less, about the same or more DENI Gel than the amount of your usual emollient(s) which you would have expected to use? (n=19)



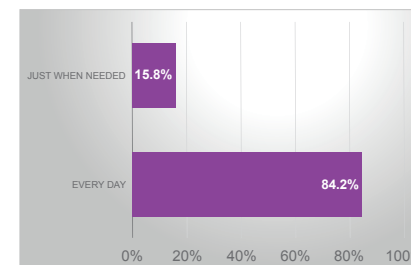
Q2: Overall, would you say your skin condition has benefited from using DENI Gel? (n=19)

In the second study, patients generally used about the same amount of DENI Gel as their standard emollient (Q1) and 94% reported that they felt their skin condition had benefited from using DENI Gel (Q2). Approximately half of the patients reported that they needed to use less of their other anti-inflammatory treatments. The remainder reported that they used about the same, and nobody stated that they used more of their other anti-inflammatory treatments. Given a choice to apply the product on all affected areas or just selected areas, 89% of patients considered DENI gel suitable to apply on all affected areas (Q3), and 84% used it every day (Q4). The Medical Investigator considered that for nearly all patients, DENI Gel was a helpful and convenient addition to their treatment regime.

Reported side effects were similar in nature and frequency to those reported for emollients in general, such as temporary local stinging etc, especially on excoriated skin.



Q3: Did you apply DENI gel to all affected skin areas, or only to selected areas? (n=19)



Q4: Did you use DENI gel every day over the past four weeks, or just when you felt you needed it? (n=19)

Table 1. Performance statements (n=43)

| Question | Positive responses |
|--|--------------------|
| The consistency of the gel is pleasant | 95.3% |
| The gel is easy to apply | 100% |
| The gel absorbs well into my skin | 93.0% |
| The gel soothes my skin | 86.0% |
| The gel makes my skin feel softer | 81.4% |
| The gel makes my skin feel comfortable | 86.0% |
| The gel makes my skin feel smoother | 83.7% |
| The gel makes my skin feel moisturised | 90.7% |

Conclusion

A new anti-inflammatory emollient, DENI gel, appears to be a helpful and convenient addition to the treatment armamentarium for eczema and psoriasis that may reduce reliance on topical corticosteroids and immunomodulators.