An investigation of the performance and safety of an emollient cream

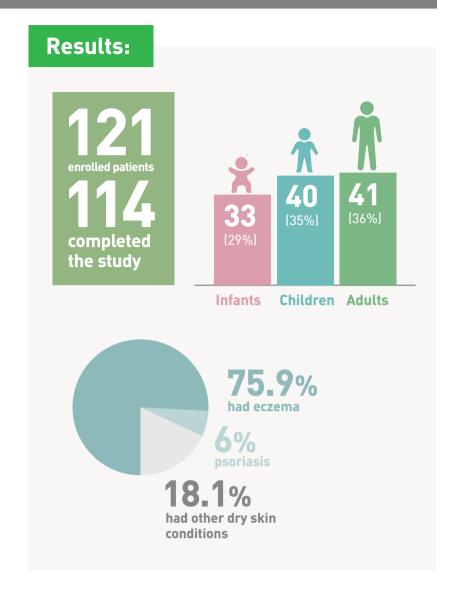
Authors: August S., Granier S., Tighe M., Tbaily L. 2020, data on file. A prospective clinical investigation of Epaderm® Cream to confirm the performance and safety in adult and paediatric patients with eczema, psoriasis and other dry skin conditions.

Introduction and objectives

A prospective clinical study to assess the performance and safety of an emollient and cleanser made from 25% (w/w) paraffin for softening, moisturising, reducing skin water loss, and 5% (w/w) glycerine for hydration. This was used across a wide range of ages including infants. The objectives were the subject's clinical evaluations and safety parameters.

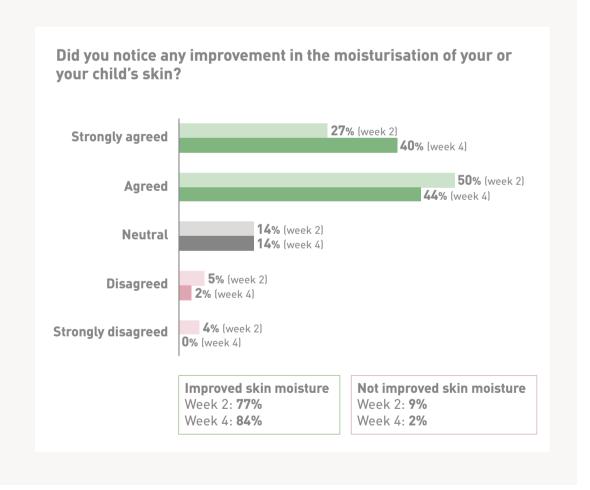
Materials and Methods

A prospective, non-randomised, single-arm clinical investigation was divided into three groups; **infants** (0-36 months), **children** (3-18 years) and **adults** (> 18 years). Each subject was followed over 4 weeks, with a visit at baseline, week 2, and 4. Statistical analysis of the data was performed.



By week 2 and week 4:

- √ 84% of subjects, strongly agreed or agreed that the cream improved skin moisture
- ✓ 86% of subjects, strongly agreed or agreed that there was an improvement in skin softness
- ✓ The skin was well hydrated after treatment
- ✓ Overall the cream was rated 'good' or 'excellent' by the patients or their parents in 88.5% of infants and 83.2% of all patients



Conclusions

- The emollient cream was well tolerated across all groups including infants.
- The cream improved skin moisturisation and softness over two weeks in all age groups across all indications.
- The cream based on feedback from subjects and clinicians performed well in terms of dry skin/xerosis, skin hydration and itching.

