

**Title:****Steroid-sparing potential of Daleuton cream in Atopic Dermatitis patients****Authors**

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**Background**

Daleuton is the active ingredient dihomono- $\gamma$ -linolenic acid (DGLA), an endogenous lipid found in healthy human skin. Daleuton targets the signs and symptoms of atopic dermatitis (AD) by exerting anti-inflammatory, anti-bacterial and anti-pruritic effects.

**Objective**

To investigate the efficacy and steroid-sparing potential of 5% daleuton cream in adults with moderate-to-severe AD.

**Methods**

In a multicentre, randomized, double-blind, vehicle-controlled study, adults with moderate-to-severe AD were randomised 1:1, to apply a potent topical steroid (mometasone furoate) and either 5% daleuton or vehicle cream once daily for 7 days; followed by 28 days with either 5% daleuton twice daily (BID) or vehicle BID. The primary endpoint was change in Eczema Area and Severity Index (EASI) from baseline to day 35. Secondary endpoints included changes in Investigator Global Assessment (IGA) score, SCORAD, pruritus Visual Analogue Scale (VAS) and Dermatology Life Quality Index (DLQI).

**Results**

42 patients with moderate-to-severe AD were enrolled in and completed the trial. For all efficacy variables there was a rapid improvement from baseline to day 7 following topical steroid administration. Mean clinician-reported (EASI, IGA, SCORAD) and patient-reported scores (VAS, DLQI) decreased further from day 7 to day 35 for the daleuton group. Disease severity scores increased in the vehicle group. A trend towards a steroid-sparing effect was seen for EASI in the daleuton arm with greater improvements observed from baseline compared to vehicle at day 35/EOT (61% v 45%). The differentiation between 5% daleuton and vehicle was more pronounced at day 42 (follow up) for multiple endpoints including EASI, IGA, SCORAD and DLQI.

Daleuton was well-tolerated with no trends in adverse events and a safety profile similar to vehicle cream.

**Conclusion**

The absence of a treatment plateau and sustained improvements from baseline following steroid withdrawal suggest that daleuton may have potential for the prevention of flares in patients with AD.