PAEDIATRIC DERMATOLOGY

EFFICACY OF MAXIMAL-USE FIXED-DOSE COMBINATION CALCIPOTRIOL 50µG/G (CAL) AND BETAMETHASONE DIPROPIONATE 0.5MG/G (BD) CUTANEOUS FOAM IN ADOLESCENT PATIENTS WITH PSORIASIS: RESULTS FROM A PHASE 2 TRIAL

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Introduction: Fixed-dose combination calcipotriol 50µg/g (Cal) and betamethasone dipropionate 0.5mg/g (BD) foam is approved for treatment of psoriasis vulgaris in adults.

Objective: Report efficacy of maximal-use Cal/BD foam in patients (aged 12–<17 years), with psoriasis (NCT02387853).

Materials and Methods: A Phase 2, international, prospective, open-label, non-controlled study. Adolescent patients with body (trunk and/or limbs) and scalp psoriasis received Cal/BD foam (once daily for 4 weeks); treatment continued even if lesions cleared at Week (W)2.
The per-protocol set included patients in the hypothalamic-pituitary-axis (HPA) cohort (at least moderate psoriasis according to physician's global assessment of disease severity [affecting ≥10% of body and ≥20% of scalp area (BSA and SSA, respectively)] and normal HPA function at screening).
Primary outcome: safety (reported separately); secondary outcome: efficacy (full-analysis set). Post-hoc analyses in the per-protocol set included treatment success (PGA; 'clear'/'almost clear' skin in patients with moderate disease, and 'clear' in patients with mild disease at baseline); percentage change from baseline in PASI; change in itch (visual analogue scale used). Change from baseline in physician-assessed extent of psoriasis (percentage BSA and SSA affected) was also investigated.

Results: 106 patients received Cal/BD foam; 33 were included in the per-protocol set (median age 14 years, 100% with moderate psoriasis).
Treatment success according to PGA at W4 on the body and scalp was achieved by 93.9%

(31/33) and 97.0% (32/33) of patients, respectively. Patients experienced mean improvements in PASI from baseline of 59.9% and 85.9% at W2 and W4, respectively. Mean itch score at baseline was 43.5, improving to 10.7 and 1.0 at W2 and W4, respectively. Percentage BSA and SSA affected improved from baseline (16.3 and 55.5, respectively) to W4 (3.9 and 5.5, respectively).

Conclusions: In this study, maximal-use, Cal/BD foam provided consistent improvements in efficacy measures for patients.