PAEDIATRIC DERMATOLOGY

SAFETY AND PHARMACOKINETICS OF MAXIMAL-USE FIXED-DOSE COMBINATION CALCIPOTRIOL 50µG/G AND BETAMETHASONE DIPROPIONATE 0.5MG/G CUTANEOUS FOAM IN ADOLESCENT PATIENTS WITH PSORIASIS: PHASE 2 TRIAL RESULTS

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Introduction: Fixed-dose combination Cal/BD foam is approved for treatment of psoriasis vulgaris in adults.

Objective: Report effects of maximal-use Cal/BD foam on calcium metabolism, HPA axis, and PK in adolescent patients, with plaque psoriasis (NCT02387853).

Materials and Methods: A Phase 2, international, prospective, open-label, non-controlled study. Patients (aged 12–<17 years) with body and scalp psoriasis received Cal/BD foam (once daily for 4 weeks); treatment continued even if lesions cleared at Week (W)2.
In the HPA-axis cohort, patients had at least moderate psoriasis according to physician's global assessment of disease severity (≥10% of body and ≥20% of scalp area) and normal HPA function at screening.
Primary outcome: safety. In this cohort included: serum cortisol ≤18 µg/dL 30 min post-ACTH challenge and change from baseline in calcium excretion and calcium:creatinine ratios. Secondary outcomes included efficacy (reported separately). PK was also assessed.

Results: 106 patients received Cal/BD; 34 were included in the HPA cohort. One withdrew before W2 (excluded from the per-protocol set [n=33; median age 14 years] but included in the HPA 24-hour-urine set n=34).
Post-ACTH challenge at W4, three patients had minor decreases in serum cortisol at 30 min, compared with baseline; two of these patients were completely normalized at 60 min. No PK analytes were detectable in these patients.
No mean increases from baseline in 24-hour-urinary-calcium excretion and calcium:creatinine ratio at W4.

BD and its metabolite betamethasone 17-propionate were quantifiable in 12 (36%) and 6 (18%) patients, respectively; PK parameters were calculable for one such patient. Calcipotriol and its metabolite, MC1080, were not quantifiable in any samples.

Conclusions: Maximal-use, fixed-dose combination Cal/BD foam resulted in no clinically relevant changes in calcium metabolism. Three patients had minor decreases in serum cortisol, with no detectable PK analytes. Low levels of BD and its metabolite were detectable in some patients.