

[Skip to main content](#)

Clobex Shampoo (Clobetasol Propionate Shampoo)

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In clinical trials with CLOBEX® Shampoo (clobetasol propionate shampoo) , the following adverse reactions have been reported: burning/stinging, pruritus, edema, folliculitis, acne, dry skin, irritant dermatitis, alopecia, urticaria, skin atrophy and telangiectasia.

The table below summarizes selected adverse events that occurred in at least 1% of subjects in the Phase 2 and 3 studies for scalp psoriasis.

Summary of Selected Adverse Events ≥ 1% by Body System

Vehicle Shampoo N=127	Clobetasol Propionate Shampoo N=558	Body System
28 (22.0%)	49 (8.8%)	Skin and Appendages
16 (12.6%)	26 (4.7%)	Discomfort Skin
9 (7.1%)	3 (0.5%)	Pruritus
12 (9.4%)	33 (5.9%)	Body As A Whole
1 (0.8%)	10 (1.8%)	Headache

The following additional local adverse reactions have been reported infrequently with other topical corticosteroids, and they may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximately decreasing order of occurrence: hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and miliaria.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.