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Calcipotriene and Betamethasone Dipropionate Topical Suspension (Taclonex Scalp)

??? ??????: 30 ??????/?????? 2017

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directed compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Clinical Trials on the Scalp

The rates of adverse reactions given below were derived from randomized, multicenter, prospective vehicle- and/or active controlled clinical trials in subjects with scalp psoriasis. Subjects applied study product once daily for 8 weeks, and the median weekly dose was 12.6 g. Adverse reactions that occurred in ? 1% of subjects treated with Taclonex® Topical Suspension and at a rate higher than in subjects treated with vehicle are presented in Table 1:

Table 1 : Number and Percentage with Adverse Reactions in Scalp Psoriasis Trials (Events Reported by ? 1% of Subjects and for Which a Relationship is Possible)

Vehicle N=173	Calcipotriene in vehicle N=979	Betamethasone dipropionate in vehicle N=1,214	Taclonex® Topical Suspension N=1,953	
# of subjects (%)				Event
0 (0%)	5 (1%)	12 (1%)	16 (1%)	Folliculitis
0 (0%)	29 (3%)	10 (1%)	13 (1%)	Burning sensation of skin

Other less common adverse reactions (< 1% but > 0.1%) were, in decreasing order of incidence: acne, exacerbation of psoriasis, eye irritation, and pustular rash.

In a 52-week trial, adverse reactions that were reported by > 1% of subjects treated with Taclonex® Topical Suspension were pruritus (3.6%), psoriasis (2.4%), erythema (2.1%), skin irritation (1.4%), and folliculitis (1.2%).

Clinical Trials on the Body

In randomized, multicenter, prospective vehicle- and/or active controlled clinical trials in subjects with plaque psoriasis on non-scalp areas, subjects applied study product once daily for 8 weeks. A total of 824 subjects were treated with Taclonex® Topical Suspension and the median weekly dose was 22.6 g. There were no adverse reactions that occurred in ? 1% of subjects treated with Taclonex® Topical Suspension and at a rate higher than in subjects treated with vehicle.

Other less common adverse reactions (< 1% but > 0.1%) were, in decreasing order of incidence: rash and folliculitis.