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Clobex Spray (Clobetasol Propionate Spray)

??? ??????: 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 directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In controlled, clinical trials with CLOBEX® Spray, 0.05%, the most common adverse reaction was burning at the site of application [40% of subjects treated with CLOBEX® Spray, 0.05% and 47% of subjects treated with Spray Vehicle]. Other commonly reported adverse reactions for CLOBEX® Spray, 0.05% and Spray Vehicle, respectively, are noted in Table 1.

Table 1 : Commonly Occurring Adverse Reactions (? 1% Incidence)

Vehicle Spray (N=120)	Clobetasol Propionate 0.05% Spray (N=120)	Adverse Reaction
		System Organ Class
56 (47%)	50 (42%)	General disorders and administration site conditions
56 (47%)	48 (40%)	Application site burning
0 (0%)	2 (2%)	Application site dryness
0 (0%)	1 (1%)	Application site irritation
2 (2%)	1 (1%)	Application site pain
0 (0%)	1 (1%)	Application site pigmentation changes
3 (3%)	4 (3%)	Application site pruritus
12 (10%)	17 (14%)	Infections and infestations
3 (3%)	6 (5%)	Nasopharyngitis
0 (0%)	1 (1%)	Pharyngitis streptococcal
2 (2%)	10 (8%)	Upper respiratory tract infection
2 (2%)	4 (3%)	Skin and subcutaneous tissue disorders
0 (0%)	2 (2%)	Eczema asteatotic

Most local adverse reactions were rated as mild to moderate and they are not affected by age, race or gender.

Systemic absorption of topical corticosteroids has produced hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Postmarketing Experience

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been identified during post-approval use of CLOBEX® Spray, 0.05%.

Burning, pruritus, erythema, pain, irritation, rash, peeling, urticaria, and contact dermatitis.**Skin:**