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Differin Gel .3% (Adapalene)

??? ??????: 30 ?????2/????? 2017

Clinical Studies Experience

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

In the multi-center, controlled clinical trial, signs and symptoms of local cutaneous irritation were monitored in 258 acne patients who used DIFFERIN Gel, 0.3% once daily for 12 weeks. Of the patients who experienced cutaneous irritation (erythema, scaling, dryness, and/or burning/stinging), the majority of cases were mild to moderate in severity, occurred early in treatment and decreased thereafter. The incidence of local cutaneous irritation with DIFFERIN Gel, 0.3% from the controlled clinical study is provided in the following table:

Table 1: Physician assessed local cutaneous irritation with DIPPERIN Gel

Incidence of Local Cutaneous Irritation with DIFFERIN Gel, 0.3% from Controlled Clinical Study (N = 253*)			
Maximum Severity Scores Higher Than Baseline			
Severe	Moderate	Mild	
1 (0.4%)	33 (13.0%)	66 (26.1%)	Erythema
3 (1.2%)	47 (18.6%)	110 (43.5%)	Scaling
2 (0.8%)	43 (17.0%)	113 (44.7%)	Dryness
9 (3.6%)	36 (14.2%)	72 (28.5%)	Burning/Stinging

* Total number of subjects with local cutaneous data for at least one post-Baseline evaluation.

Table 2: Patient reported local cutaneous adverse reactions with DIFFERIN Gel

Vehicle Gel N=134	DIFFERIN (adapalene) Gel, 0.3% N=258	
6 (4.5%)	57(22.1%)	Related* Adverse Reactions
2(1.5%)	36(14%)	Dry Skin
0 (0.0%)	15(5.8%)	Skin Discomfort
0 (0.0%)	4(1.6%)	Desquamation

* Selected adverse reactions defined by investigator as Possibly, Probably or Definitely Related

Related adverse reactions from the controlled clinical trial that occurred in greater than 1% of patients who used DIFFERIN Gel, 0.3% once daily included: dry skin (14.0%), skin discomfort (5.8%), pruritus (1.9%), desquamation (1.6%), and sunburn (1.2%). The following selected adverse reactions occurred in less than 1% of patients: acne flare, contact dermatitis, eyelid edema, conjunctivitis, erythema, pruritus, skin discoloration, rash, and eczema.

In a one-year, open-label safety study of 551 patients with acne who received DIFFERIN Gel, 0.3%, the pattern of adverse reactions was similar to the 12-week controlled study.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of adapalene: skin irritation, application site pain, face edema, eyelid edema, lip swelling, and angioedema. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the

frequency or establish a causal relationship to drug exposure.