Skip to main content

Fabior (Tazarotene)

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Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in 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 clinical practice.

The safety data reflect exposure to Fabior Foam in 744 patients with acne vulgaris. Patients were 12 years to 45 years of age and were treated once daily in the evening for 12 weeks. Adverse reactions reported in ? 1% of patients treated with Fabior Foam are presented in Table 1. Most adverse reactions were mild to moderate in severity. Severe adverse reactions represented 3.0% of the patients treated. Overall, 2.6% (20/744) of patients discontinued Fabior Foam because of local skin reactions.

Table 1: Incidence of Adverse Reactions in ? 1 % of Patients Treated with Fabior Foam

Vehicle Foam N=741	Fabior Foam N=744	
19 (3)	163 (22)	Patients with any adverse reaction, n (%)
9 (1)	107 (14)	Application site irritation
8 (1)	50 (7)	Application site dryness
3 (< 1)	48 (6)	Application site erythema
3 (< 1)	44 (6)	Application site exfoliation
0	9 (1)	Application site pain
3 (< 1)	8 (1)	Application site photosensitivity (including sunburn)
3 (< 1)	7 (1)	Application site pruritus
1 (< 1)	6 (1)	Application site dermatitis

Additional adverse reactions that were reported in < 1% of patients treated with Fabior Foam included application site reactions (including discoloration, discomfort, edema, rash and swelling), dermatitis, impetigo and pruritus.

Local skin reactions, dryness, erythema, and peeling actively assessed by the investigator and burning/stinging and itching reported by the patient were evaluated at baseline, during treatment, and end of treatment. During the 12 weeks of treatment, each local skin reaction peaked at week 2 and gradually reduced thereafter with the continued use of Fabior Foam.