CLINICAL UPDATE

Brand Name	Fabior™
Generic Name	tazarotene
Drug Manufacturer	Stiefel Laboratories, Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New formulation

FDA APPROVAL DATE

May 11, 2012

LAUNCH DATE

Jan 11, 2017

REVIEW DESIGNATION

STANDARD

TYPE OF REVIEW

Type 3 - New Dosage Form

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION(S) FOR USE

Tazarotene is a retinoid indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

MECHANISMS OF ACTION

The mechanism of tazarotene action in acne vulgaris is not defined. However, the basis of tazarotene's therapeutic effect in acne may be due to its anti-hyperproliferative, normalizing-of-differentiation and anti-inflammatory effects. Tazarotene inhibited corneocyte accumulation in rhino mouse skin and cross-linked envelope formation in cultured human keratinocytes. The clinical significance of these findings is unknown.

DOSAGE FORM(S) AND STRENGTH(S)

0.1%, foam

DOSE & ADMINISTRATION

Apply a thin layer to the entire affected areas of the face and/or upper trunk once daily in the evening. Avoid the eyes, lips, and mucous membranes. Wash hands after application.

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EFFICACY

In 2 multi-center, randomized, double-blind, vehicle-controlled trials, a total of 1,485 subjects with moderate-to-severe acne vulgaris were randomized 1:1 to Fabior™ Foam or vehicle applied once daily for 12 weeks. Acne severity was evaluated using lesion counts and the 6-point Investigator's Global Assessment (IGA) scale.

Investigator's Global Assessment Scale

Grade	Description	
0	Clear	Clear skin with no inflammatory or non-inflammatory lesions.
1	Almost clear	Rare non-inflammatory lesions with no more than rare papules.
2	Mild	Greater than Grade 1, some non-inflammatory lesions with no more than a few inflammatory lesions (papules/pustules only, no nodular lesions).
3	Moderate	Greater than Grade 2, up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion.
4	Severe	Greater than Grade 3, up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions.
5	Very severe	Many non-inflammatory and inflammatory lesions and more than a few nodular lesions. May have cystic lesions.

Table: Reductions in Lesion Counts and Improvements in Investigator's Global Assessment at Week 12

	Trial 1		Trial 2	
	Fabior™ Foam N = 371	**Vehicle Foam N = 372**	**Fabior™ Foam N = 373**	**Vehicle Foam N = 369**
Inflammatory Lesions				
Mean absolute reduction from Baseline	18.0	14.0	18.0	15.0
Mean percent reduction from Baseline	58%	45%	55%	45%
Non-inflammatory Lesions				
Mean absolute reduction from Baseline	28.0	17.0	26.0	18.0
Mean percent reduction from Baseline	55%	33%	57%	41%
Total Lesions				
Mean absolute reduction from Baseline	46.0	31.0	43.0	33.0
Mean percent reduction from Baseline	56%	39%	56%	43%
Investigator's Global Assessment (IGA), n (%)				
Minimum 2-grade improvement *and* IGA of 0 or 1	107 (29%)	60 (16%)	103 (28%)	49 (13%)