FIRST TIME GENERIC APPROVAL

Brand Name	Targretin®
Generic Name	bexarotene
Drug Manufacturer	Amneal Pharmaceuticals NY LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First time generic

FDA APPROVAL DATE

April 27, 2022

LAUNCH DATE

May 24, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 215398

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Bexarotene gel, 1% is indicated for the topical treatment of cutaneous lesions in patients with CTCL (stage IA and IB) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

MECHANISMS OF ACTION

Bexarotene selectively binds and activates retinoid X receptor subtypes (RXRα, RXRβ, RXRγ). RXRs can form heterodimers with various receptor partners such as retinoic acid receptors (RARs), vitamin D receptor, thyroid receptor, and peroxisome proliferator activator receptors (PPARs). Once activated, these receptors function as transcription factors that regulate the expression of genes that control cellular differentiation and proliferation. Bexarotene inhibits the growth in vitro of some tumor cell lines of hematopoietic and squamous cell origin. It also induces tumor regression in vivo in some animal models. The exact mechanism of action of bexarotene in the treatment of cutaneous T-cell lymphoma (CTCL) is unknown.

DOSE FORM AND STRENGTH

Bexarotene gel 1% (60 g) tube

DOSE & ADMINISTRATION

- Bexarotene gel, 1% should be initially applied once every other day for the first week.

- The application frequency should be increased at weekly intervals to once daily, then twice daily, then three times daily and finally four times daily according to individual lesion tolerance.
- If application site toxicity occurs, the application frequency can be reduced. Should severe irritation occur, application of drug can be temporarily discontinued for a few days until the symptoms subside.