Aklief (trifarotene)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Aklief
- **Generic name:** Trifarotene
- **Pharmacological class:** Retinoid
- **Strength and Formulation:** 0.005%; cream
- **Manufacturer:** Galderma Laboratories
- **How supplied:** Cream—30g, 45g, 75g
- **Legal Classification:** Rx

Aklief


Rx Only
NDC 0299-5935-45
AKLIEF®
(trifarotene)
Cream, 0.005%
— PUMP —
For topical use only
NET WT.
45g
GALDERMA
AKLIEF®
(trifarotene)
Cream, 0.005%
— PUMP —
For topical use only
NET WT. 45g
GALDERMA

Indication

- Topical treatment of **acne vulgaris** in patients 9 years of age and older

Dosage and Administration

- **<9yrs: not established**
- ≥9yrs: apply a thin layer to affected areas once daily in the evening
- Face: 1 pump actuation
- Upper trunk: 2 pump actuations; may use 1 additional pump actuation for middle and lower back, if needed
- Use of a moisturizer is recommended as frequently as needed from the initiation of treatment

Considerations for Special Populations

- **Pregnancy:** available data have not identified drug-associated risk; cases of birth defects have been reported in pregnant women exposed to other topical retinoids
- **Nursing mothers**: to minimize exposure, use on the smallest area of skin and for the shortest duration possible while breastfeeding; do not apply directly to nipple/areola
- **Pediatric**: <9yrs: not established
- **Geriatric:** trials did not include patients ≥65 years

Warnings/Precautions

- Not for oral, ophthalmic, or intravaginal use
- Avoid eyes, lips, paranasal creases, mucous membranes
- Do not use on cuts, abrasions, eczematous or sunburned skin
- Advise patients to use a moisturizer, reduce frequency, suspend, or discontinue therapy based on severity of skin irritation
- Minimize exposure to sun and UV light; if unavoidable, use sunscreen and protective clothing

Interactions

- Avoid waxing on treated skin areas

Adverse Reactions

- **Most common (≥1%)**: application site irritation, application site pruritus, sunburn

Mechanism of Action

- Trifarotene is an agonist of retinoic acid receptors (RAR), with particular activity at the gamma subtype of RAR
- Stimulation of RAR results in modulation of target genes which are associated with various processes, including cell differentiation and mediation of inflammation
- The exact mechanism by which trifarotene ameliorates acne is unknown

Clinical Trials

- The approval of Aklief was based on data from 2 parallel group, double-blind, vehicle-controlled clinical trials conducted in 2420 patients with moderate facial and truncal acne vulgaris

- The co-primary end points of the studies were based on success as measured by 5-point Investigator's Global Assessment (IGA) scale for the face and a 5-point Physician's Global Assessment (PGA) scale for the trunk; success was defined as a score of 1 (almost clear) or 0 (clear) and at least a 2-grade improvement from baseline to Week 12

Clinical Trials

- Results at Week 12 for facial acne showed that 29.4% of patients in Study 1 and 42.3% of patients in Study 2 treated with Aklief had IGA success compared with 19.5% and 25.7% of placebo-treated patients, respectively

- As for the trunk, 35.7% of patients in Study 1 and 42.6% of patients in Study 2 treated with Aklief achieved PGA success vs 25.0% and 29.9% with placebo, respectively

New Product Monograph

- For more information view the product monograph available at:

https://www.empr.com/drug/aklief/