

Trifarotene INN

Composition

Each gram Trifera 0.005% cream contains Trifarotene INN 50 mcg.

Pharmacology

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 process by which trifarotene ameliorates acne is unknown.

Indication

Trifera Cream is a retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Dosage & Administration

Route of administration : Topical

Apply a thin layer of Trifarotene cream to the affected areas once daily, in the evening, on clean and dry skin. The use of a moisturizer is recommended as frequently as needed from the initiation of treatment. Avoid contact with the eyes, lips, paranasal creases, mucous membranes. Trifarotene cream is intended for topical use only. Not for oral, ophthalmic or intravaginal use.

Contraindications

The following conditions are contraindicated with this drug:

- Sunburn
- Eczema

Warning & Precautions

Skin irritation

Patients using Trifarotene cream may experience erythema, scaling, dryness and stinging/burning. Maximum severity of these reactions typically occurred within the first 4 weeks of treatment and severity decreased with continued use of the medication. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of application of Trifarotene cream, or suspend use temporarily. If severe reactions persist, the treatment may be discontinued.

Avoid application of Trifarotene cream to cuts, abrasions, eczematous or sunburned skin. Use of "waxing" as a depilatory method should be avoided on skin treated with Trifarotene cream.

Ultraviolet Light and Environmental Exposure

Minimize unprotected exposure to ultraviolet rays (including sunlight and sunlamps) during treatment with Trifarotene cream. Warn patients who normally experience high levels of sun exposure and those with inherent sensitivity to sun to exercise caution. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided.

Side Effects

Common side effects: Most common adverse reactions (incidence $\geq 1\%$) in patients treated with Trifarotene cream were application site irritation, application site pruritus and sunburn.

Rare side effects: A very serious allergic reaction to this drug is rare. Patients should get medical help right away if noticed any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing, skin discoloration, puffy skin, sudden pain at the site of medicine application.

Use in Pregnancy & Lactation

Pregnancy : Available data from clinical trials with Trifarotene cream use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

Lactation : The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Trifarotene cream and any potential adverse effects on the breastfed infant from Trifarotene cream or from the underlying maternal condition.

Use in Children & Geriatric

Safety and effectiveness of Trifarotene cream have not been established in pediatric patients below the age of 9 years.

Clinical trials of Trifarotene cream did not include any subjects age 65 years and over to determine whether they respond differently than younger subjects.

Drug Interactions

Topical application of Trifarotene cream is not expected to affect the circulating concentrations of oral hormonal contraceptives containing ethinyl estradiol and levonorgestrel.

Overdose

This medicine may be harmful if swallowed. If someone has overdosed and has serious symptoms such as passing out or trouble breathing have to consult with physician.

Storage

Store below 25°C temperature & dry place, protect from light.
Keep all medicines out of reach of children.

Packing

Each carton contains a tube of 15 g cream and an insert.

* Further information is available on request.



Manufactured by:

The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh

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