



# Lumiface™ Cream

Trifarotene INN 0.005%

## Presentation

**Lumiface™ Cream:** Each gram 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.

## Indication and uses

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

## Dosage and Administration

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.

## Side effects

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

## Contraindication

Trifarotene cream is contraindicated in patients with a history of hypersensitivity to Trifarotene or any other components of this product.

## Warning & precaution

### *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, or 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. Patients should be warned 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.

## Use in Pregnancy and Lactation

### *Australian TGA pregnancy category D.*

Trifarotene cream is contraindicated during pregnancy or in women planning a pregnancy. If the patient becomes pregnant while taking this drug, treatment should be discontinued.

There are no data on the presence of Trifarotene in human milk, the effects on the breastfed infant, or the effects on milk production.

## Drug interactions

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

## Overdosage

There is no experience of overdosage with Trifarotene cream.

## Storage condition

Do not store above 30 °C. Keep away from light and out of the reach of children.

## Commercial pack

**Lumiface™ Cream:** Each laminated tube contains 15 gm cream.