

# Zonyra

Trifarotene INN



## Composition

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. The exact process by which Trifarotene ameliorates acne is unknown.

## Indication

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.

## Contraindications

N/A

## Side effects

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

## Precaution & Warning

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. 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.

## Drug interactions

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

## Use in pregnancy & lactation

Pregnancy – Category C

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.

Nursing Mothers

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.

## Pediatric Use

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

## Geriatric Use

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

## Storage

Do not store above 25°C. Protect from light. Keep out of reach of children.

## Packaging

Each carton contains a tube of 15 g cream and a leaflet.

Manufactured by



**Ziska Pharmaceuticals Ltd.**  
Kaliakoir, Gazipur, Bangladesh