

Soritene[®]

Tazarotene 0.10% (w/w)

Cream

Description

Tazarotene is a retinoid prodrug which is converted to its active form, the cognate carboxylic acid of tazarotene, by rapid deesterification in animals and man. In cell culture and in vitro models of skin, tazarotene suppresses expression of MRP8, a marker of inflammation present in the epidermis of psoriasis patients at high levels. In human keratinocyte cultures, it inhibits cornified envelope formation, whose build-up is an element of the psoriatic scale.

Indications

Tazarotene is used to treat plaque psoriasis of the skin. It also works to treat acne on the face.

Dosage and Administration

For psoriasis: Tazarotene cream should be applied once per day, in the evening, to psoriatic lesions, using enough (2 mg/cm²) to cover only the lesion with a thin film. If a bath or shower is taken prior to application, the skin should be dried before applying the cream. If emollients are used, they should be applied at least one hour before application of Tazarotene cream.

For acne: Cleanse the face gently. After the skin is dry, apply a thin layer (2mg/cm²) of Tazarotene cream 0.1% once per day, in the evening, to the skin areas where acne lesions appear. Use enough to cover the entire affected area.

Contraindications

Retinoids may cause fetal harm when administered to a pregnant woman. Tazarotene cream is contraindicated in women who are or may become pregnant. If

this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued and the patient should be apprised of the potential hazard to the fetus. Women of child-bearing potential should be warned to the potential risk and use adequate birth-control measures when Tazarotene cream is used.

Adverse Reactions

The most frequent adverse events reported with Tazarotene cream were limited to the skin. Those occurring in 10 to 23% of patients, in descending order, included pruritus, erythema and burning. For acne treatment, in 10 to 30% patients, it is reported desquamation, dry skin, face pain, irritation and stinging sensation.

Precaution

Tazarotene cream should be applied only to the affected areas. For external use only. Avoid contact with eyes, eyelids and mouth. If contact with eyes occurs, rinse thoroughly with water. Retinoids should not be used on eczematous skin, as they may cause severe irritation. Patients must be warned to use sunscreens and protective clothing when using Tazarotene cream. Some individuals may experience excessive pruritus, burning, skin redness or peeling. If these effects occur, the medication should either be discontinued until the integrity of the skin is restored, or the dosing should be reduced.

High Risk Group

Pregnancy: Tazarotene is not recommended during pregnancy. It has been shown to cause serious birth defects and problems in animals. Be sure you have discussed this

with your doctor.

Nursing Mothers: It is not known whether tazarotene passes into breast milk. However, Tazarotene is not recommended during breast-feeding because it may cause unwanted effects in nursing babies.

Pediatric Use: Studies of this medicine have been done only in adult patients, and there is no specific information comparing use of Tazarotene in children up to 12 years of age (gel) and up to 18 years of age (cream) with use in other age groups.

Elderly Use (Over 65 yr.): There is no specific information comparing the use of Tazarotene in the elderly with use in other age groups.

Drug Interactions

Concomitant dermatologic medications and cosmetics that have a strong drying effect should be avoided. It is also advisable to "rest" a patient's skin until the effects of such preparations subside before use of Tazarotene cream is begun.

Topical steroid may be hazardous in psoriasis; careful patient supervision is important. Consider if infection spreads. Do not use near a naked flame.

Commercial Pack

Soritene[®] cream: Tube containing 25 g cream and each gram contains Tazarotene INN 1mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH

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