

Cosmotrin®

(Tretinoin Cream)

Description

Cosmotrin cream is a topical anti-acne preparation containing Tretinoin USP 0.025%. Topical Tretinoin decreases cohesiveness of follicular epithelial cells with decreased microcomedo formation. Additionally Tretinoin stimulates mitotic activity and increases turnover of follicular epithelial cells, causing extrusion of the comedones, papules and pustules.

Indications

For topical application in the treatment of acne vulgaris in which comedones, papules and pustules predominate.

Dosage and Administration

Cosmotrin cream should be applied sparingly to the whole affected area once or twice daily. The skin should be thoroughly cleaned and dried before application. Patient should be advised that 6 to 8 weeks of treatment may be required before a therapeutic effect is observed. Moisturisers and cosmetics may be used during treatment with Cosmotrin cream but should not be applied to the skin at the same time. Astringent toiletries should be avoided.

Contraindications

Tretinoin is contraindicated to those who are highly sensitive to any of the ingredients. This cream should not be used in patients with a personal or family history of cutaneous epithelioma (skin cancer).

Precautions

Avoid contact of Tretinoin with lips, mouth, eyes, eyelids, nostrils or other mucous membrane. If contact in these areas occur, careful washing with water is recommended. Apply the cream to sensitive areas of skin, such as the neck, with caution. Do not use it on broken, eczematous or sun burned skin.

Drug Interactions

Other topical acne treatments should be used with caution during treatment with Tretinoin. Particular caution should be exercised when

using preparation containing a peeling agent for example benzoyl peroxide. It is also possible to apply Tretinoin and benzoyl peroxide alternately. The suggested regimens are either Tretinoin in the morning and benzoyl peroxide in the evening or the preparations should be used on alternate days.

Side Effects

Initial external application of Tretinoin generally may cause burning or slight irritation. Erythema and peeling at the site of application. If irritation becomes severe and persists, application should be discontinued and consultation with physician is required, if necessary.

Use in Special Population

Pregnancy and lactation :There is an inadequate evidence of the safety of topically applied Tretinoin cream during pregnancy. Tretinoin has been associated with teratogenicity in human when administered systemically. So, the cream should not be used during pregnancy and lactation.

Commercial Pack

Cosmotrin[®] Cream : Tube containing 10 g cream, each gram contains Tretinoin USP 0.25 mg.