



Nilac[®] Gel

Tretinoin
Anti-Acne

COMPOSITION

Nilac[®] gel : Each 100 gm Nilac[®] gel contains 0.025 gm Tretinoin USP.

PHARMACOLOGY

Tretinoin is structurally and pharmacologically related to vitamin A. Current evidence suggests that topical Tretinoin decreases cohesiveness of follicular epithelial cells with decreased microcomedone formation. Additionally, Tretinoin stimulates mitotic activity and increases turnover of follicular epithelial cells, causing extrusion of the comedones.

INDICATION

1. For the treatment of acne vulgaris in which comedones, papules and pustules predominate.
2. For the treatment of hyperpigmentation, roughness and fine wrinkling of photodamaged skin due to chronic sun exposure.

DOSAGE AND ADMINISTRATION

Nilac[®] gel should be applied once or twice a day, before retiring, to the skin where lesions appear, using enough to cover the entire affected area lightly. The frequency of application can be adjusted to obtain maximum clinical efficacy with minimal erythema and scaling.

If Nilac[®] gel is applied excessively, no more rapid or better results will be obtained and marked redness, peeling or discomfort may occur. Should this occur accidentally or through over-enthusiastic use, application should be discontinued for few days.

Patience is needed in this treatment, since the therapeutic effects will not usually be observed until after 6-8 weeks of treatment. During the early weeks of treatment, an apparent exacerbation of inflammatory lesions may occur. This is due to the action of the medication on deep, previously unseen comedones and papules. Once the acne lesions have responded satisfactorily, it should be possible to maintain the improvement with less frequent applications.

Moisturizers and cosmetics may be used during treatment with Nilac[®] gel but should not be applied to the skin at the same time. The skin should be thoroughly washed before application of Nilac[®] gel. Astringent toiletries should be avoided.

CONTRAINDICATION AND PRECAUTION

Tretinoin is contraindicated in patients who are allergic to this drug. It is contraindicated in pregnancy or suspected pregnancy. It is also contraindicated in personal or familial history of cutaneous epithelioma.

Local irritation: The presence of cutaneous irritative signs (e.g. erythema, peeling, pruritus, sunburn, etc.) should prohibit initiation or recommencement of treatment with Tretinoin until the symptoms resolve.

Tretinoin has been reported to cause severe irritation on eczematous skin and should be used with caution in patients with this condition.

Exposure to sunlight: Exposure to sunlight, including ultraviolet sun-lamps, should be avoided or minimised during the use of Tretinoin.

General precaution: Before application of Tretinoin, areas to be treated should be cleansed thoroughly. Abstain from washing the treated area frequently; twice daily is sufficient. Use of mild soap is recommended. Dry the skin without rubbing.

Avoid contact with eyes, eyelids, nostrils, mouth and mucous membranes. If contact in these areas occurs, careful washing with water is recommended.

SIDE EFFECT

True allergic contact dermatitis is rare but a primary irritant dermatitis, manifesting itself as irritation, erythema, peeling and sensation of warmth, is common. Slight stinging is common as a mild reaction in many people but usually settles with continuous use and/or reduction in frequency of application of the drug.

DRUG INTERACTION

Particular caution should be exercised in using preparations containing peeling agents (i.e. sulfur, resorcinol, benzoyl peroxide or salicylic acid). Use of topical preparations with high concentrations of alcohol, menthol, spices or lime- such as shaving lotions, astringents and perfume- should be avoided, especially during initial therapy.

USE IN PREGNANCY AND LACTATION

Tretinoin is contraindicated in pregnancy or suspected pregnancy. The drug should be avoided by breast feeding mothers.

Nilac[®] Gel

STORAGE CONDITION

Store in a cool and dry place, away from light. Keep out of reach of children.

HOW SUPPLIED

Nilac[®] (Tretinoin) 0.025% gel : Tube containing 10 gm gel.

