

# ACNE-STOP (Cream)

Tretinoin (0.025 % - 0.05 %)



THIS PRODUCT IS TO BE USED ONLY ACCORDING TO YOUR DOCTOR'S INSTRUCTIONS, AND IT SHOULD NOT BE APPLIED TO OTHER AREAS OF THE BODY OR TO OTHER LESIONS. THE LONG-TERM SAFETY AND EFFECTIVENESS OF THIS PRODUCT IN OTHER DISORDERS HAVE NOT BEEN EVALUATED.  
For Topical Use Only

#### **COMPOSITION:** Each 1 g of cream contains:

Tretinoin: 0.25 mg or 0.5 mg (0.025%, 0.05%).

**Excipients:** stearic acid, isopropyl myristate, emulgin B2, propylene glycol, stearyl alcohol, xanthan gum, sorbic acid, Butylated Hydroxytoluene , purified water.

#### **CLINICAL PHARMACOLOGY:**

Topical tretinoin decreases cohesiveness of follicular epithelial cells with decreased microcomedo formation. Additionally, tretinoin stimulates mitotic activity and increased turnover of follicular epithelial cells causing extrusion of the comedones.

#### **INDICATIONS AND USE:**

Tretinoin is indicated for topical application in the treatment of

- Acne vulgaris.
- Other acnes (acneiform eruptions): drug-induced acnes induced by corticosteroids, barbiturates , etc.
- Favre and Racouchot disease: cutaneous elastidosis with cysts and comedones.

#### **CONTRAINDICATIONS:**

Use of the product should be discontinued if hypersensitivity to any of the ingredients is noted.

#### **PRECAUTIONS:**

If a reaction suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued. Exposure to sunlight, including sunlamps, should be minimized during the use of Tretinoin, and patients with sunburn should be advised not to use the product until fully recovered. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, also may be irritating to patients under treatment with tretinoin. Tretinoin should be kept away from the eyes, the mouth, angles of the nose, and mucous membranes. Tretinoin has been reported to cause severe irritation on eczematous skin and should be used with utmost caution in patients with this condition.

#### **ADVERSE REACTIONS:**

The skin of certain sensitive individuals may become excessively red, edematous, blistered. If these effects occur, the medication should either be discontinued until the integrity of the skin is restored, or the medication should be adjusted to a level the patient can tolerate. Temporary hyper- or hypopigmentation has been reported with repeated application of Tretinoin.

#### **DRUG INTERACTIONS:**

Concomitant topical medication, medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices or lime should be used with caution because of possible interaction with tretinoin. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid with the drug. It also is advisable to "rest" a patient's skin until the effects of such preparations subside before use of the drug is begun.

#### **Pregnancy:**

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Tretinoin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### **Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when the drug is administered to a nursing woman.

#### **DOSE AND ADMINISTRATION:**

Cream should be applied once a day, before retiring, to the skin where acne lesions appear, using enough to cover the entire affected area lightly.

During the early weeks of therapy, an apparent exacerbation of inflammatory lesions may occur. This is due to the action of the medication on deep, previously unseen lesions and should not be considered a reason to discontinue therapy.

Therapeutic results should be noticed after two to three weeks but more than six weeks of therapy may be required before definite beneficial effects are seen.

Once the acne lesions have responded satisfactorily, it may be possible to maintain the improvement with less frequent applications, or other dosage forms.

Patients treated with (tretinoin) acne treatment may use cosmetics, but the area to be treated should be cleansed thoroughly before the medication is applied.

#### **OVERDOSAGE:**

If medication is applied excessively, no more rapid or better results will be obtained and marked redness, peeling, or discomfort may occur. Oral ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of Vitamin A.

#### **Presentation:**

A tube contains 20 g of cream/carton box.

#### **Storage condition:**

- Store at room temperature, (15 -25) °C.
- For topical use only.
- Prescription only medicine.
- Keep out of reach of children.
- It is not given for pregnant woman.

#### **\* THIS IS A MEDICAMENT \***



- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

( Council of Arab Ministers )

( Union of Arab Pharmacists )

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