

RETINOMYCIN®

Topical gel

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about RETINOMYCIN

RETINOMYCIN gel contains tretinoin 0.025% and erythromycin 4% with the following excipients: hydroxypropyl methylcellulose, ethanol

RETINOMYCIN is indicated for the treatment of acne vulgaris, primarily where comedones, papules and pustules predominate.

The effect of RETINOMYCIN is due to the antibacterial activity of erythromycin and to the effect of tretinoin, which increases the turnover of epidermal cells and loosens the cells compacted to form comedones.

The way to use RETINOMYCIN

This product is to be used only according to your doctor's instructions.

RETINOMYCIN gel should be applied to the affected area once a day, preferably in the evening, to the skin where acne lesions appear, using enough to cover the entire affected area lightly. The area under treatment should be thoroughly cleansed with a mild soap, and dried, followed by application of the gel in gentle rubbing motion, using fingertips to apply medication. Wash your hands afterwards.

Applications are then adapted according to the skin's reactions.

In the absence of any local irritation, frequency of applications may be increased up to twice daily.

Application may be accompanied by a transitory feeling of warmth, stinging sensation or peeling during the early days of treatment. It is just your skin adjusting to the gel and this usually subsides within two to four weeks.

An exacerbation of acne lesions may occur during the early weeks of therapy. This is due, in part, to the action of the medication on deep lesions and should not be considered a reason to discontinue therapy.

Should these effects become excessively troublesome, consult your doctor.

Once your acne is under control, your doctor may instruct you to follow up your treatment by applying the gel 2 or 3 times per week to maintain the improved state.

Duration of treatment

Therapeutic results may be noticed after 2 to 6 weeks of treatment; however, results may not be optimal until after 12 or 14 weeks of treatment. Do not be discouraged if you see no immediate improvement. Do not stop treatment at the first signs of improvement.

Alterations of dose frequency and duration of treatment should be closely monitored by your doctor.

In case of overdose

An overdose of this medication is unlikely to occur. If medication is applied excessively, no more rapid or better results will be obtained and marked redness, peeling, or discomfort may occur. If you suspect an overdose, irritation develops, or if the gel has been ingested, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Apply the missed dose as soon as you remember unless the next application is near. Go on applying the next scheduled dose as directed. Do not apply a double dose at once.

Contraindications

This drug should not be used in case of hypersensitivity to any of the components.

Precautions

- This medication is for external use only. Avoid contact with the eyes, corners of the nose, mouth, open wounds and all mucous membranes. If contact occurs, rinse thoroughly with water.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should not be used during pregnancy. Caution should be exercised when it is administered to a nursing woman.
- Before starting therapy, it is preferable to apply the gel on a reduced area of the skin to test the sensibility to the product.
- Avoid excessive exposure to sunlight while using this medication. Use a sunscreen and wear protective clothing when exposure to the sun is unavoidable. Patients with sunburn should not use the product until fully recovered. Weather extremes, such as wind or cold, also may be irritating to patients under treatment with this gel.
- If a reaction suggesting sensitivity or irritations occur, usage of the medication should be discontinued.

Association with other medications

Please inform your doctor if you are using any other medication.

Avoid products that can increase skin irritation such as abrasive soaps or astringent skin cleansers (perfumed or alcoholic products).

Adverse reactions

The skin of certain sensitive individuals may become excessively red, edematous blistered or crusted. If these effects occur, the medication should either be discontinued until the integrity of the skin is restored, or the medication dosing frequency should be adjusted temporarily to a level you can tolerate. People having a fine skin or blond hair are more susceptible to these reactions.

Temporary hyper- or hypo-pigmentation has been reported with repeated application.

Adverse effects are reversible upon discontinuation.

Report to your doctor any signs of local adverse reactions.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack presentation

RETINOMYCIN topical gel, tretinoin 0.025% and erythromycin 4%, tube of 40 g

Revision date: 12/2011

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