

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Acnetrim Solution at concentration of 2% w/v

Active ingredient

Every 10 ml of solution contain 0.2 grams of erythromycin

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Topical antibiotic treatment of acne, particularly inflammatory acne with papules and pustules.

Therapeutic group:

anti-acne medicines for topical use, anti-infectives.

Erythromycin, the active ingredient in this medicine, penetrates the excretory ducts of the sebaceous glands in the skin, where it acts specifically against bacteria which play an important role in the development of acne. The alcoholic basis supports the antibacterial effect of erythromycin, also dissolving the excessive sebum produced in acne.

2. Before using this medicine

Do not use this medicine:

- if you are sensitive (allergic) to erythromycin or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Talk to your doctor or pharmacist before using Acnetrim. Take special care with Acnetrim when using it on the face. Prevent contact of Acnetrim with your eyes.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

There are no known interactions with other medicines.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant, you can still use Acnetrim, because the active ingredient erythromycin in the medicine is not absorbed through the skin into the bloodstream in significant

quantities. Therefore, undesirable effects on the unborn child are not to be expected.

Breastfeeding

If you are breastfeeding, you can still use Acnetrim. However, you should make sure that the baby's mouth does not come into contact with parts of the body where you have applied Acnetrim.

Driving and using machines

No particular precautions are required.

Important information about some of this medicine's ingredients

Propylene glycol, an ingredient in the solution, may cause skin irritation.

This medicine contains 450 mg alcohol (ethanol) per 1 ml of solution. It may cause a burning sensation on damaged skin.

Do not light a cigarette or expose to fire until the product has dried completely. Caution! Flammable substance.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Your dose and treatment will be determined only by your doctor. The recommended dosage is usually:

After cleaning the skin, carefully apply Acnetrim over all the affected skin areas twice a day: in the morning and in the evening. In cases where excessive dryness develops in the treated areas, your doctor will consider reducing the frequency of treatment to once a day. Apply the medicine according to the doctor's instructions and complete the full course of treatment. To prevent your skin from drying and the condition getting worse, it is advisable to avoid washing the affected areas too often.

Opening instructions: To first open the bottle, press the center of the sponge firmly with a clean finger.

For external use only.

Do not exceed the recommended dose.

Treatment duration

Treatment with Acnetrim should not last longer than 4-6 weeks.

If you feel that the effect of Acnetrim is too strong or too weak, contact your doctor or pharmacist.

If you have applied more than the doctor prescribed or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.

If you stop using Acnetrim

Always consult your doctor if you want to stop the treatment.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Acnetrim may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor immediately if:

- you experience a serious skin reaction: a red scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (its frequency has not been established yet).

Other side effects

Very rare side effects (less than 1 in 10,000 patients): dryness, redness, stinging and itchy skin.

In very rare cases (less than 1 in 10,000 patients) these symptoms may be the expression of a hypersensitivity reaction to the active ingredient or to any of the other ingredients in Acnetrim (allergic contact eczema).

After a prolonged period of treatment the symptoms may worsen due to the development of resistance (insensitivity of the bacteria) and inflammation of the skin (dermatitis) caused by certain bacteria.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il> In addition, you can report by email to: safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C.

Shelf-life after first opening

- Acnetrim can be used for up to 6 months after first opening.
- Do not dispose of medicines via wastewater (toilet or sink). Ask at your pharmacy where to dispose of medicines you no longer use. This will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

alcohol, propylene glycol, oleyl alcohol, perfume essence.

What the medicine looks like and what the contents of the package are

Acnetrim is a clear, colorless/pale yellow solution.

Acnetrim is available in glass bottles containing 25 ml solution.

Manufacturer and registration holder: Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in April 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

035-38-25621-00

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

