

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (MEDICINAL PRODUCTS) - 1986**

The medicine is dispensed with a doctor's prescription only

ROZEX
GEL
0.75% W/W

The active ingredient:

Metronidazole 0.75% w/w

For the list of inactive and allergenic ingredients in the medicinal product – see section 6 'Further information'.

Also see 'Important information about some of the ingredients of the medicine' in section 2.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rozex is intended for topical application for the treatment of inflammatory papules, pustules and erythema of rosacea.

Therapeutic group: Chemical medicinal product for external use.

Rozex contains the active ingredient metronidazole. Metronidazole is an antiprotozoal and antibacterial agent from the nitroimidazole group that acts against a wide range of disease-inducing microorganisms, which has been proven to help treat infection and inflammation in certain skin problems, such as rosacea.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are hypersensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (for the list of inactive ingredients - see section 6 'Further information'). An allergic reaction can include rash or itch.

Special warnings regarding use of the medicine:

- If you are sensitive to any food or medicine, inform the doctor before using the medicine.
- Avoid contact of the gel with the eyes. If the gel accidentally contacted the eyes, wash the area well with a large amount of lukewarm water or an eye wash.
- When using the medicine, avoid exposure to strong sunlight (including tanning) and/or ultraviolet (UV) light, e.g., solarium, tanning lights.

- Do not use the medicine unnecessarily and/or for a prolonged period of time without consulting the doctor.

Before starting treatment, tell your doctor if you suffer or have suffered in the past, from a blood disorder. In such a condition, do not use Rozex unless your doctor has instructed you to do so.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking the following medicines (note that the list below indicates the active ingredients in the medicines. If you are unsure if you are using one of these medicines – consult the doctor or pharmacist):

Anticoagulants/blood thinners (e.g., warfarin and dicoumarin) – Rozex may affect their activity.

Use of the medicine and alcohol consumption:

When metronidazole is taken as an oral medicine, it can cause a reaction with alcohol. Since Rozex is for use on the skin, this reaction is less likely. However, it is recommended not to drink alcohol while using the medicine.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, use of the medicine is not recommended, unless the doctor considers that it is essential. If you are pregnant, think you are pregnant, are planning a pregnancy or are breast-feeding, consult the doctor before using the medicine.

Driving and operating machinery:

Rozex has no effect on the ability to drive and operate machinery.

Children and adolescents:

This medicine is not intended for children.

Important information about some of the ingredients of the medicine:

- The ingredients methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (which may occur at a later stage).
- Each gram of the medicinal product contains 30 mg propylene glycol, equivalent to 3% w/w, which may cause skin irritation.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicinal product according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicinal product.

The dosage and treatment regimen will be determined by the doctor only.

How to use:

- First, wash and dry the affected areas of the skin.

- Apply a thin layer of Rozex gel to all the affected areas. Be careful not to get it in the eyes.
- Gently massage so that it penetrates the skin well.
- Always replace the cap and wash your hands thoroughly after use.

The usual dosage is generally:

Apply a thin layer of gel twice a day (morning and evening) or as recommended by the doctor.

The doctor will decide on the recommended duration of treatment (usually about 3 to 4 months) to treat rosacea.

Do not exceed the recommended dose. Cosmetic products that do not clog or tighten the skin pores can be used after the medicine is used and absorbed into the skin.

Attention!

- Do not swallow! This medicine is intended for external use only.
- Avoid contact with the eyes.

If you took an overdose or accidentally swallowed the medicine, or if a child has swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to use the medicine

While the gel works best when used regularly according to the instructions, do not be concerned if you forgot to use the gel at the right time. Continue using the gel as usual as soon as you remember, according to the instructions for use.

If you stop taking the medicine

Rosacea may react slowly to antibiotic treatment. It is important that you continue using Rozex until your doctor tells you to stop.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Rozex may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effects (occur in 1-10 in 100 users):

- skin effects such as: itching, irritation, dryness, redness, discomfort (burning, pain, stinging).
- worsening of rosacea.

Uncommon side effects (occur in 1-10 in 1,000 users):

- numbness, tingling and prickling in the fingers and toes.
- metallic taste in the mouth.
- nausea.

Side effects of unknown frequency (effects whose frequencies have not been determined):

- contact dermatitis.
- swelling of the face.
- peeling skin.
- teary eyes, if applied near the eyes.

If skin irritation occurs, either use the gel less often or even stop using it until the irritation settles down. Consult a doctor or pharmacist if needed.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or by clicking the following link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store at room temperature (15°C-25°C).
Can be used for 3 months after first opening.
- Do not discard medicines in the wastewater or the household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Purified water, propylene glycol, carbomer 940, methyl parahydroxybenzoate, disodium edetate, propyl parahydroxybenzoate, sodium hydroxide.

What does the medicine look like and what are the contents of the package?

Rozex is a clear-yellowish homogenous gel which may take on a slightly brown tint over time. The tube of gel contains 30 grams.

Manufacturer: Laboratories Galderma, Z.I. Montdésir, 74540 Alby-sur-Chéran, France.

Registration holder: A.M.I. Medical Technologies Limited, Hanagar 22, Hod Hasharon, 4501317, Israel.

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

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