

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Rozex Gel

Active ingredient:

Metronidazole (0.75% w/w)

For a list of inactive ingredients, please see section 6.

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

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to 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?

Rozex is intended for topical treatment of inflammation, redness and irritation, due to Rosacea.

Therapeutic group:

Antibacterial substance of the Imidazole group for topical use.

2. Before using the medicine

Do not use the medicine if:

Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (for a list of inactive ingredients - please see section 6).

Special warnings regarding the use of this medicine:

- If you are sensitive to any type of food or medicine, inform your doctor before using this medicine.
- Avoid contact of the gel with the eyes. If the gel accidentally comes in contact with the eyes, wash the area with a large quantity of lukewarm water.
- While using the medicine, avoid exposure to strong sunlight and/or to ultra-violet (UV) light e.g. solariums, tanning lamps.
- Do not use the medicine unnecessarily and/or for a prolonged period, without consulting your doctor.

Before starting the treatment, tell your doctor if you suffer or have suffered in the past from a blood system disorder.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements.

In particular, inform your doctor or pharmacist if you are taking any of the following medicines (it should be noted that the following list mentions the active ingredients in the medicines. If you are not sure whether you are taking one of these medicines, please consult your doctor or pharmacist):

- Medicines that prevent blood clotting (e.g. warfarin).

Use of this medicine and alcohol consumption:

When metronidazole is taken by mouth, it can react with alcohol. This reaction is less likely with Rozex because it is applied on the skin. However, it is recommended not to drink alcohol while using this medicine.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, consult with your doctor before using this medicine.

Use in children:

This medicine is not usually intended for children.

Important information about some of the medicine's ingredients:

- The ingredients methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (that may possibly appear at a later stage).
- The ingredient propylene glycol may cause skin irritation.

3. How to use this medicine?

Always use according to the doctor's instructions.

You should check with your doctor or pharmacist if you are not sure.

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

Directions for use:

- First wash properly (with mild soap) and dry gently the affected areas of the skin.
- Apply a thin layer of Rozex gel to all the affected areas and massage gently into the skin.
- After use, replace the cap and wash your hands.

The standard dosage is usually:

Apply a thin layer of the gel twice a day (morning and evening).

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

Do not exceed the recommended dose.

Cosmetics may be used after applying the medicine and its absorption into the skin.

Attention!

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

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

If you forgot to use the medicine on time, continue using the gel as usual when you remember, according to the directions for use.

You should continue the treatment as recommended by your doctor.

Even if your health condition improves, do not stop the treatment with this medicine without consulting your doctor.

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

If you have further questions regarding the use of the medicine, consult your doctor or pharmacist.

4. Side effects

Like any medicine, the use of Rozex may cause side effects in some users. If these side effects persist or are bothersome or get worse, please consult your doctor. Do not be alarmed while reading the list of side effects; you may not suffer from any of them.

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

- Skin reactions, such as: itching, irritation, dryness, redness, discomfort (burning, pain, stinging).
- Worsening of the disease (Rosacea).

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

- Numbness and tingling in the fingers or toes.
- Metallic taste in the mouth.
- Nausea.

Side effects of unknown frequency:

- Skin inflammation from contact (contact dermatitis).
- Swelling of the face.
- Peeling skin (exfoliation).
- Teary eyes, in case of application near the eyes.

If a side effect appears, or if one of the side effects worsens, or if you suffer from a side effect which is not mentioned in the leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. 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: at room temperature (at a temperature of 15°C-25°C).
After the first opening, it may be used within 3 months.

6. Further information

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

Propylene glycol, carbomer 940, methyl parahydroxybenzoate, disodium edetate, propyl parahydroxybenzoate, sodium hydroxide, purified water.

What does the medicine look like and what does the package contain?

Rozex is a clear-light yellow gel. The gel tube contains 30 grams.

Manufacturer: Laboratories Galderma, France.

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301

Medicine registration number in the National Medicine Registry of the Ministry of Health: 062 18 26970

This leaflet was checked and approved by the Ministry of Health in July 2016.