

ROZEX[®] GEL

Metronidazole 0.75%

Consumer Medication Information Leaflet (RiMUP)

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What Rozex Gel is used for

Rozex Gel is used as topical application to treat pimples, *pustules* (spots) and redness that develops with *rosacea* condition.

How Rozex Gel works

Rozex Gel contains active ingredient *metronidazole* which acts against harmful microorganisms to help control infection and inflammation in the skin due to *rosacea*.

Before you use Rozex Gel

- When you must not use it

Rozex Gel must not be used in individuals with a history of hypersensitivity to *metronidazole*, parabens, or other ingredients of the formulation.

- Before you start to use it

Rozex Gel has been reported to cause tearing of the eyes. Therefore, contact with the eyes should be avoided. If local irritations occur, patient should be directed to use less frequently, discontinue use temporarily or discontinue use until further instruction.

- Taking other medicines

Rozex Gel is expected to have minimal interactions with other medications. Individuals who are receiving anticoagulant treatment should inform their doctor, as absorption of metronidazole into the bloodstream may increase the anticoagulant (blood thinning) effect of such medication.

How to use Rozex Gel

- How much to use

Apply and rub in a thin film of Rozex Gel twice daily, morning and evening, to the entire affected areas after washing.

- When to use it

Apply twice daily, morning and evening. Cosmetics may be used after application of Rozex Gel.

How long to use it

Improvement should be noticed within three weeks. Your doctor will decide how long you need to use Rozex Gel to keep your *rosacea* under control.

If you forget to use it

Although this gel works best if you use it regularly as directed, don't worry if you forget to use your gel at the right time.

When you do remember, start using it again in the same way as before

If you use too much (overdose)

This product is for use on the skin only. Do not swallow it. If you accidentally do so, seek medical advice.

While you are using it

- Things you must do

Area to be treated should be cleansed and dried before application of Rozex Gel. Always use this medicine exactly as your doctor had told you. Check with your doctor or pharmacist if you are not sure

- Things you must not do

Do not take Rozex Gel if you are allergic to *metronidazole* or any of the other ingredients of this medicine. An allergic reaction may include a rash or itching

- Things to be careful of

- If you suffer from any blood disorders do not use Rozex Gel unless your doctor says you can.
- This product should not be used in children.
- Using Rozex Gel could interfere with drugs used to thin the blood (anticoagulants) such as *warfarin* and *dicoumarin*. Contact your doctor for advice if you are taking medicines to thin your blood, or if you suffer from any other blood disorders.
- If you are pregnant or breast-feeding, it may not be advisable to use this product, unless your doctor considers it essential.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects reported include skin irritation, dryness, redness, burning sensation and watery (tearing) eyes.

If skin irritation should occur either

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use the gel a little less often or even stop using it until the irritation settles down.

Seek medical advice from your doctor or pharmacist if necessary

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [(Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Rozex Gel**- Storage**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not freeze.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description**- What it looks like**

• Rozex Gel is a clear to pale yellow gel which may turn to slightly brown colour over time.

• It is available in a 5g, 15g, or 30g tube, only on prescription from your doctor. Not all pack sizes may be marketed

- Ingredients**Active ingredient(s)**

The active substance is *metronidazole*. Each gram of Rozex Gel contains 7.5mg of *metronidazole*

Inactive ingredients:

The other ingredients are *carbomer 940, disodium edetate, methyl parahydroxybenzoate, propyl parahydroxybenzoate, propylene glycol, sodium hydroxide* (for pH adjustment) and purified water.

- MAL number:

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Manufacturer

Laboratoires Galderma,
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Product Registration Holder:

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