

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rozex Cutaneous Emulsion 0.75% w/w

Metronidazole

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Rozex is and what it is used for
2. Before you use Rozex
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1. What Rozex is and what it is used for

- Your doctor has prescribed this emulsion for your skin condition, rosacea.
- It helps to treat the pimples, pustules (spots) and redness found with this condition.
- Rozex contains the active substance metronidazole. Metronidazole belongs to a group of medicines called antiprotozoal and antibacterial agents and has been shown to help to control infection and inflammation in certain skin problems, such as rosacea.

2. Before you use Rozex

Do not use Rozex

- if you are allergic (hypersensitive) to metronidazole or any of the other ingredients of Rozex. Please check by reading the list of ingredients in section 6. If you answer yes, you must inform your doctor before starting treatment.

Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

Take special care with Rozex

- Do not get the emulsion in your eyes. If you do, rinse thoroughly with large amounts of warm water or eye wash.
- If you suffer from any blood disorders do not use Rozex unless your doctor says you can.
- This product should not be used in children.
- Do not go out into strong sunlight (including sun-bathing) and avoid exposure to ultra-violet light (eg solariums, sun-lamps) while you are using this product.
- Avoid prolonged and unnecessary use of this medicine.

Using other medicines

- Using Rozex could interfere with drugs used to reduce blood clotting (anticoagulants) such as warfarin and dicoumarin.

Contact your doctor for advice if you are taking medicines to reduce blood clotting, or if you suffer from any other blood disorders.

- You should not drink alcohol while you are using Rozex.

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Using Rozex Emulsion with food and drink

Metronidazole taken by mouth can react with alcohol. This reaction is unlikely with Rozex Emulsion because it is only applied on the skin. However, you are advised not to drink alcohol while you are using Rozex Emulsion.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, it may not be advisable to use this product, unless your doctor considers it essential.

Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Rozex

Rozex contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Rozex

Always use Rozex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and the elderly

- First wash and dry the affected areas of your skin.
- Apply a thin layer of emulsion to the affected areas – be careful not to get it in your eyes.
- Rub the emulsion in well.
- Always replace the cap and wash your hands after use.
- Your emulsion should be used in this way twice a day, (morning and evening), or as advised by your doctor.
- Your doctor will decide how long you need to use Rozex to keep your rosacea under control.

If you use more Rozex than you should or accidentally swallow the emulsion

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

If you forget to use Rozex

- Although this emulsion works best if you use it regularly as directed, don't worry if you forget to use your emulsion at the right time. When you do remember, start using it again in the same way as before.

If you stop taking Rozex

Rosacea may respond slowly to antibiotics. It is important that you continue using Rozex until your doctor tells you to stop.

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

4. Possible side effects

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

Common side effects (occur in less than 1 in 10 patients)

- dry skin
- redness of the skin (erythema)
- itching of the skin (pruritus)
- skin discomfort (burning, pain of skin / stinging)
- skin irritation
- worsening of rosacea

Uncommon side effects (occur in less than 1 in 100 patients)

- numbness (hypothesia) and tingling (paraesthesia) in the fingers or toes
- metallic taste (dysgeusia)
- feeling sick (nausea)

Unknown frequency of occurrence (cannot be estimated from the available data)

- contact dermatitis

If skin irritation should occur either use the emulsion a little less often or even stop using it until the irritation settles down. Seek medical advice from your doctor or pharmacist if necessary.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Rozex

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Rozex contains

- Rozex contains 0.75% w/w of the active substance metronidazole.
- The other ingredients are carbomer 941, benzyl alcohol, glycerol, macrogol 400, polyethylene glycol 21 stearyl ether, stearyl macrogolglyceride, stearyl alcohol, light liquid paraffin, cyclomethicone, potassium sorbate, lactic acid and/or sodium hydroxide and purified water.

What Rozex looks like and contents of the pack

- Rozex is a white to beige coloured fluid lotion.
- It is available in 15g (sample pack only), 30g or 50g tube, and 30 ml or 60 ml bottles only on prescription from your doctor.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts. WD17 1DS, UK (PA 590/10/3)

Manufacturer: Laboratoires Galderma, ZI- Montdésir, 74540, Alby-sur-Chéran, France

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