

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rozex 0.75% w/w Cutaneous Emulsion

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.

In this leaflet:

1. What Rozex is and what it is used for
2. Before you use Rozex
3. How to use Rozex
4. Possible side effects
5. How to store Rozex
6. Further information

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 (see section 6 for other ingredients). An allergic reaction may include a rash or itching.

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 and anyone under 18 years of age
- Do not go out into strong sunlight, or use UV 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.

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

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 Emulsion

Rozex Emulsion contains stearyl alcohol and potassium sorbate 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.

- First wash and dry the affected areas of your skin.
- Apply a thin layer of the emulsion to the affected areas - be careful not to get it in your eyes.
- Rub the emulsion well in.
- 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 (may affect up to 1 in 10 people): Skin reactions such as burning and stinging pain sensation, redness and dryness, irritation and itching of the skin, worsening of rosacea.

Uncommon (may affect up to 1 in 100 people): Nausea, metal taste in the mouth and tingling or numbness of arms or legs.

Not known (frequency cannot be estimated from the available data): Contact dermatitis.

Avoid contact with the eyes, mouth, angles of the nose and other mucous surfaces such as the lining of your nose. If accidental contact should occur, rinse thoroughly with warm water.

If skin irritation should occur either use the lotion 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.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

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 and carton. The expiry date refers to the last day of that month.
- Discard the tube or bottle 60 days after first opening.
- Do not store above 25°C, in its original tube.
- Do not refrigerate.

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 (E1519), glycerol, macrogol 400, steareth-21, glyceryl stearate/PEG-100 stearate, stearyl alcohol, light liquid paraffin, cyclomethicone, potassium sorbate (E202), lactic acid, sodium hydroxide and purified water.

What Rozex looks like and contents of the pack

- Rozex is a white to off-white emulsion. It is available in a 15g, 30 g or 50 g tube and a 60ml bottle, 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 (PL 10590/0036)

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

This leaflet was last approved in 04/2011.

Is this leaflet hard to see or read?

This leaflet is available in a text only format at www.xpil.medicines.org.uk.

Alternatively to get this leaflet in large print, Braille or as an audio CD, call the RNIB Medicine Leaflet line on **0800 198 5000**, quoting product code PL10590/0036.