

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rozex[®] 0.75% w/w Gel

(metronidazole)

This product is available as the above name but will be referred to as Rozex throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rozex is and what it is used for
2. What you need to know before you use Rozex
3. How to use Rozex
4. Possible side effects
5. How to store Rozex
6. Contents of the pack and other information

1. What Rozex is and what it is used for

- Your doctor has prescribed this gel 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. What you need to know before you use Rozex

Do not use Rozex

- If you are allergic to metronidazole or any of the other ingredients of this medicine (see section 6 for other ingredients). An allergic reaction may include a rash or itching.
- If you are affected by Cockayne syndrome. Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with products containing metronidazole.

Warnings and precautions

Talk to your doctor or pharmacist before using Rozex.

- Do not get the gel in your eyes. If you do so, 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 (e.g. solariums, sun-lamps) while you are using this product.
- Avoid prolonged and unnecessary use of this medicine.

Other medicines and Rozex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Using Rozex 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.

Rozex with alcohol

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

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. 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 taking this medicine.

Rozex contains:

- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed),
- 30mg propylene glycol (E1520) in each gram which is equivalent to 3% w/w, it may cause skin irritation.

3. How to use Rozex

Always use this medicine exactly as your doctor had told you. 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 the gel to all the affected areas - be careful also not to get it in your eyes.
- Rub the gel in well.
- Always replace the cap and wash your hands after use.
- Your gel 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 gel

- 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 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 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common: may affect up to 1 in 10 people

- 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: may affect up to 1 in 100 people

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

Not known: frequency cannot be estimated from the available data

- contact dermatitis
- swelling of the face
- peeling skin (exfoliation)

If skin irritation should occur either 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Rozex

- **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.
- 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.
- If the gel becomes discoloured or show any signs of deterioration, seek the advice of your pharmacist.

6. Contents of the pack and other information**What Rozex contains**

- The active substance is metronidazole. Each gram of gel contains 7.5 mg of metronidazole.
- The other ingredients are carbomer 940, disodium edetate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), sodium hydroxide (for pH adjustment) and purified water.

What Rozex looks like and contents of the pack

- Rozex is a colourless to pale yellow gel which may turn to slightly brown colour over time.
- Rozex is available in 30 g aluminium tubes.

PL: 15814/1850

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Manufactured by Laboratoires Galderma, Alby-sur-Cheran, France.

Procured from within the EU and repackaged by the Product Licence holder: OPD Laboratories Limited, Unit 5-7, Colonial Way, Watford, WD24 4YR.

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Metronidazole 0.75% w/w Gel

This product is available as the above name but will be referred to as Metronidazole Gel throughout this leaflet.

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- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
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What is in this leaflet

1. What Metronidazole Gel is and what it is used for
2. What you need to know before you use Metronidazole Gel
3. How to use Metronidazole Gel
4. Possible side effects
5. How to store Metronidazole Gel
6. Contents of the pack and other information

1. What Metronidazole Gel is and what it is used for

- Your doctor has prescribed this gel for your skin condition, rosacea.
- It helps to treat the pimples, pustules (spots) and redness found with this condition.
- Metronidazole Gel 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. What you need to know before you use Metronidazole Gel

Do not use Metronidazole Gel

- If you are allergic to metronidazole or any of the other ingredients of this medicine (see section 6 for other ingredients). An allergic reaction may include a rash or itching.
- If you are affected by Cockayne syndrome. Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with products containing metronidazole.

Warnings and precautions

Talk to your doctor or pharmacist before using Metronidazole Gel.

- Do not get the gel in your eyes. If you do so, rinse thoroughly with large amounts of warm water or eye wash.
- If you suffer from any blood disorders do not use Metronidazole Gel 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 (e.g. solariums, sun-lamps) while you are using this product.
- Avoid prolonged and unnecessary use of this medicine.

Other medicines and Metronidazole Gel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Using Metronidazole 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.

Metronidazole Gel with alcohol

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

Pregnancy and breast-feeding

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Adults and the elderly

- First wash and dry the affected areas of your skin.
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- Rub the gel in well.
- Always replace the cap and wash your hands after use.
- Your gel 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 Metronidazole Gel to keep your rosacea under control.

If you use more Metronidazole Gel than you should or accidentally swallow the gel

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Uncommon: may affect up to 1 in 100 people

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Not known: frequency cannot be estimated from the available data

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