

Metrogel 0.75% Gel

metronidazole

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Metrogel 0.75% Gel

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 Metrogel is and what it is used for
2. Before you use Metrogel
3. How to use Metrogel
4. Possible side effects
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6. Further information

1. What Metrogel 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.
- Metrogel 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 Metrogel

Do not use Metrogel

- If you are allergic (hypersensitive) to metronidazole or any of the other ingredients of Metrogel (see section 6 for other ingredients). An allergic reaction may include a rash or itching.

Take special care with Metrogel

- Do not get the gel 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 Metrogel 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 Metrogel 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.

Using Metrogel with food and drink

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

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 Metrogel

Metrogel contains propylene glycol which may cause skin irritation and hydroxybenzoic acid esters which may cause allergic reactions (possibly delayed).

3. How to use Metrogel

Always use Metrogel 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 gel to all the affected areas - be careful 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 Metrogel to keep your rosacea under control.

If you use more Metrogel 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 Metrogel

- 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 Metrogel

Rosacea may respond slowly to antibiotics. It is important that you continue using Metrogel 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, Metrogel 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 (hypoesthesia) 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 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.

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 Metrogel

- Keep out of the reach and sight of children.
- Do not use Metrogel after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.
- Store it at room temperature (below 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 Metrogel contains

Metrogel contains 0.75% w/w of the active substance metronidazole. The other ingredients are phosphoric acid, hydroxybenzoic acid esters, bronopol, hydroxyethyl cellulose, propylene glycol and purified water.

What Metrogel looks like and contents of the pack

- Metrogel is a clear gel.
- Metrogel is available in 25 g and 40 g tubes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Ltd. Meridien House, 69-71 Clarendon Road, Watford, Herts. WD17 1DS, UK. (PL 10590/0035)
Manufacturer: Bioglan AB, PO Box 50310, S-202 13 Malmö, Sweden.

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