

Package leaflet: information for the user

Metrosa® 0.75% Gel

Metronidazole

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 Metrosa 0.75% Gel is and what it is used for
2. What you need to know before you use Metrosa 0.75% Gel
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1. What Metrosa 0.75% Gel is and what it is used for

Metrosa 0.75% Gel is an antiinflammatory gel to be applied on the skin.

Metrosa 0.75% Gel is used for the treatment of rosacea (redness in the face, sometimes together with additional pustules) when the condition suddenly gets worse, and the inflammation becomes troublesome.

1 g Metrosa 0.75% Gel contains 7.5 mg Metronidazole as active substance.

Metronidazole acts against some of the fungi and other organisms that can affect the skin, and also, in patients suffering from rosacea, it can relieve the condition by acting against the inflammation which happens when the condition becomes troublesome.

2. What you need to know before you use Metrosa 0.75% Gel**Do not use Metrosa 0.75% Gel**

if you are hypersensitive (allergic) to Metronidazole, propylene glycol or any of the other ingredients listed below (see 6. Contents of the pack and other information; What Metrosa 0.75% Gel contains).

Warnings and precautions

Talk to your doctor or pharmacist before using Metrosa 0.75% Gel.

Do not let the gel come into contact with the eyes and mucous membranes. If eye-contact should occur, wash the gel carefully out of the eyes with warm water.

If irritation does occur you should use Metrosa 0.75% Gel less frequently or stop temporarily. If necessary seek medical advice, please.

Do not go out into strong sunlight (sunbathing), or use UV lamps (solarium, sunlamps) while you are using this product. Metronidazole loses activity and therefore efficacy due to UV exposure.

Avoid prolonged and unnecessary use of this medicine. You shouldn't exceed the recommended duration of therapy. If required, the therapy could be recommended again and be repeated. However you should consider that an interval of 6 weeks in between has to be kept.

Use Metrosa 0.75% Gel with care if you suffer or suffered in the past from blood disorders (blood dyscrasia).

Children and adolescents

There is no adequate experience on efficacy and safety of Metrosa 0.75% Gel in children and adolescents; therefore Metrosa 0.75% Gel should not be used in children and adolescents.

Other medicines and Metrosa 0.75% Gel

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

Interaction with systemic medication is unlikely because absorption (ability to get through the skin into the body) of metronidazole following cutaneous application of Metrosa 0.75% Gel is low.

Nevertheless, it should be mentioned that reactions called disulfiram-like reactions have been reported in a small number of patients taking metronidazole and alcohol concomitantly. These reactions can include nausea, vomiting, flushing of the skin, an accelerated heart rate and shortness of breath.

Using Metrosa 0.75% Gel could interfere with drugs used to thin the blood (anticoagulants) such as warfarin and coumarin. Contact your doctor for advice if you are taking medicines to thin your blood, or if you suffer for any other blood disorders.

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

Metrosa 0.75% Gel with food, drink and alcohol

Food and meals can be consumed with only one exception: It is best not to take alcohol while using the gel, as there is a very small possibility of a reaction that might make you feel sick or nauseous.

Pregnancy and breast-feeding

Metrosa 0.75% Gel should be used in pregnancy only if it is clearly needed and recommended by your doctor. Please ask for medical advice.

You should ask your doctor for advice if you are breast-feeding whether to discontinue nursing or the drug.

Driving and using machines

You are allowed to drive and use machines since there are no effects known on the ability to drive.

Metrosa 0.75% Gel contains propylene glycol

This medicine contains 30 mg propylene glycol in 1 g gel (which is equivalent to 50 mg per application). Propylene glycol may cause skin irritation.

3. How to use Metrosa 0.75% Gel

Metrosa 0.75% Gel gel is for cutaneous use only.

Unless your doctor has told you differently, apply a 2-3 cm line of gel to the affected areas and rub it gently into the skin. Use the gel **twice each day**, for up to four weeks.

Always use Metrosa 0.75% Gel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Metronidazole should be applied in a thin layer to the affected areas of the skin twice daily, morning and evening. Areas to be treated should be washed with a mild cleanser before application. Patients may use non comedogenic and non vessel-conducting (astringent) cosmetics after application of metronidazole. The dosage does not need to be adjusted for elderly patients. The recommended duration of treatment should not be exceeded.

Use in children and adolescents

Metronidazole is not recommended for use in children due to a lack of experience on safety and efficacy.

If you use more Metrosa 0.75% Gel than you should

If you apply too much of the gel, simply wipe off the excess with a clean tissue or remove by washing with warm water. The gel is for use on the skin only. If you, or anyone else, should accidentally swallow a quantity of the gel, tell your doctor at once, or go to the nearest hospital casualty department.

If you forget to use Metrosa 0.75% Gel

If you forget to use the gel, then use it as soon as you remember, unless the next application is due within about two or three hours, in which case omit the forgotten dose.

If you stop using Metrosa 0.75% Gel

If you stop using the gel, contact your doctor or pharmacist.

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

4. Possible side effects

Like all medicines, Metrosa 0.75% Gel can cause side effects, although not everybody gets them.

The evaluation of side effects is based on the following frequencies:

Very common:	More than one patient in 10
Common:	1 to 10 patients in 100
Uncommon:	1 to 10 patients in 1,000
Rare:	1 to 10 patients in 10,000
Very rare:	Less than 1 patient in 10,000

Significant side effects, signs to look out for and what to do if you are affected:

If you are affected by any of the side effects listed below, stop using Metrosa 0.75% Gel and consult your doctor as quickly as possible.

Skin and subcutaneous tissue disorders

Common: Dry skin, erythema (abnormal redness and inflammation of the skin), pruritus (itching), rash (inflammation of the skin with reddening), skin discomfort (burning, pain of skin/ stinging), skin irritation, worsening of rosacea (chronic skin condition involving inflammation of the cheeks, nose, chin, forehead or eyelids).

Unknown frequency: Contact dermatitis (skin reaction resulting from exposure to allergens).

General disorders

Common: Pain.

Nervous System disorders

Uncommon: Hypoaesthesia (decreased sensation to normal or painful skin stimulation), paraesthesia (an abnormal or inappropriate sensation in an organ), dysgeusia (metallic taste).

Gastrointestinal disorders

Uncommon: Nausea.

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 Yellow Card Scheme, Website: 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 Metrosa 0.75% Gel

Keep this medicine out of the sight and reach of children.

Do not use Metrosa 0.75% Gel after the expiry date which is stated on the tube. The expiry date refers to the last day of that month.

Do not refrigerate or freeze the gel.

Use within 3 months of first opening.

6. Contents of the pack and other information

What Metrosa 0.75% Gel contains

- The active substance is Metronidazole. 1 g of gel contains 7.5 mg Metronidazole.
- The other ingredients are phenoxy-ethanol (Ph. Eur.), propylene glycol, hypromellose (E464) and purified water.

What Metrosa 0.75% Gel looks like and contents of the pack

It is made available as a collapsible aluminium tube containing 25 g, 30 g, 40 g or 50 g of the gel (not all pack sizes will be market at time).

Marketing Authorisation Holder and Manufacturer

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