

PACKAGE LEAFLET: INFORMATION FOR THE USER

ROZAMET

1% w/w Cream

METRONIDAZOLE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What ROZAMET is and what it is used for
2. Before you take ROZAMET
3. How to take ROZAMET
4. Possible side effects
5. How to store ROZAMET

1. WHAT ROZAMET IS AND WHAT IS IT USED FOR

- Your doctor has prescribed this cream for your skin condition, rosacea.
- It helps to treat the pimples, pustules (spots) and redness found with this condition.
- ROZAMET 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 TAKE ROZAMET

Do not use ROZAMET:

- If you are allergic to metronidazole or any of the other ingredients of this medicine. An allergic reaction may include a rash or itching.

Warnings and precautions

Talk to your doctor or pharmacist before using ROZAMET.

- Do not get the cream 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 ROZAMET 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.

Other medicines and ROZAMET

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

- Using ROZAMET 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.

ROZAMET with alcohol

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

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.

3. HOW TO TAKE ROZAMET

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

If you use more ROZAMET than you should or accidentally swallow the cream

- 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 ROZAMET

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

If you stop taking ROZAMET

Rosacea may respond slowly to antibiotics. It is important that you continue using ROZAMET 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 (hypoesthesia) 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 cream 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ROZAMET

- 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. Store in the original container.
- Do not refrigerate.

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.