

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### ROJAZOL

2% w/w cream

MICONAZOLE NITRATE

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*• 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.*

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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 • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

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

#### 1. WHAT ROJAZOL IS AND WHAT IS IT USED FOR

The name of your medicine is ROJAZOL 2% w/w cream. It is called ROJAZOL cream in this leaflet.

ROJAZOL cream contains a medicine called miconazole. This belongs to a group of medicines called 'antifungals'.

ROJAZOL cream is used for infections of the skin or nails caused by fungi including yeasts, and some bacteria.

Infections may appear on the:

- Trunk
- Hands or feet
- Scalp or outer ear
- Groin

ROJAZOL cream works by destroying the fungus and associated bacteria which may be present.

#### 2. BEFORE YOU TAKE ROJAZOL

**Do not use ROJAZOL cream:**

- If you are allergic to miconazole, any of the other ingredients of this medicine or to other similar antifungal medicines

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using ROJAZOL cream.

### **Warnings and precautions**

Keep this medicine away from your eyes. If you get any cream in your eyes, rinse with water straight away. Keep your eyes open when you rinse.

### **Other medicines and ROJAZOL Cream**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular tell your doctor if you are taking:

- Medicines to thin the blood (anticoagulants) such as warfarin. Your doctor may check that the anticoagulant is working properly

### **Pregnancy and breast-feeding**

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 using this medicine.

You may still be able to use ROJAZOL cream if your doctor thinks you need to.

### **Driving and using machines**

ROJAZOL cream is not likely to affect you being able to drive or use any tools or machines.

## **3. HOW TO TAKE ROJAZOL**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Using the cream**

- Each tube of ROJAZOL cream is sealed. You will need to use the cap to pierce the seal
- Rub the cream gently into the affected area and surrounding skin with clean fingers
- Do not put ROJAZOL cream into or near the eyes - it is for use on the skin and nails only
- Do not swallow the cream

### **For skin infections**

- Use the cream twice a day - once in the morning and again at night. Keep using the cream for at least 7 days after all signs of infection have gone away. This will stop the infection from coming back.

### **For nail infections**

- Use the cream once or twice a day. Your doctor will tell you which one.

Keep using the cream for 10 days after all signs of infection have gone away.

This will stop the infection from coming back.

### **Personal hygiene**

- Unless the affected skin is on your hands, wash your hands with soap and water after using the cream
- Washing your hands after using the cream will stop you spreading the infection to other parts of your body or to other people
- Do not allow other people to use your flannel or towel. This will stop them from getting your infection
- Clothing that touches infected skin should be washed and changed often. ROJAZOL cream is non-greasy and should not stain clothes
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### **If you swallow ROJAZOL cream**

If you swallow any cream, talk to a doctor or go to the nearest hospital casualty department straight away.

### ***If you forget to use ROJAZOL cream***

- Do not apply the forgotten dose of cream
- Apply the next dose of cream as usual and keep using the cream as your doctor has told you
- Do not use a double dose of cream to make up for a forgotten dose

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.

**Stop using ROJAZOL cream and tell your doctor straight away if you notice the following. You may need medical treatment.**

**Very rare** (affects less than 1 in 10,000 people)

- Swelling of the face, tongue or throat, difficulty swallowing or difficulty breathing
- Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin.

These may be signs of a severe allergic reaction

**Tell your doctor or pharmacist if you notice any of the following side effects:**

**Very rare** (affects less than 1 in 10,000 people)

- Burning sensation, itching, redness, or rash on the skin

**Rare** (affects less than 1 in 1,000 people)

- Local irritation of the treated area. This is much milder than an allergic reaction

### ***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 ROJAZOL***

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

Store the cream in its original packaging. Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton and tube. The expiry date refers to the last day of that month.

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.

### ***6. FURTHER INFORMATION***

#### ***What ROJAZOL cream contains***

The active substance is miconazole nitrate. Each gram (g) of ROJAZOL cream contains 20 milligrams (mg) of miconazole nitrate (2 % w/w).

#### ***What ROJAZOL cream looks like and contents of the pack***

ROJAZOL cream comes in a tube containing 30 g of a white cream.