

PACKAGE LEAFLET: INFORMATION FOR THE USER

REKONAZOL

2% cream

KETOCONAZOLE

• 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 REKONAZOL is and what it is used for
2. Before you take REKONAZOL
3. How to take REKONAZOL
4. Possible side effects
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1. WHAT REKONAZOL IS AND WHAT IS IT USED FOR

The name of your medicine is REKONAZOL 2% cream. It is called 'REKONAZOL cream' or just 'cream' in this leaflet.

REKONAZOL cream contains a medicine called ketoconazole. This belongs to a group of medicines called 'antifungals'.

REKONAZOL cream is used for fungal and yeast infections of the skin in adults.

Infections may appear on the:

- Trunk, chest or back
- Hands or feet
- Scalp or face
- Groin or genitals

REKONAZOL cream works by killing the fungus that causes the infection.

2. BEFORE YOU TAKE REKONAZOL

Do not use REKONAZOL cream:

- If you are allergic to anything in REKONAZOL cream
- For eye infections

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

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine:

- If you have recently used a cream, ointment or lotion on your skin infection that contains a steroid:
- You should continue to apply a mild steroid (such as hydrocortisone) cream, ointment or lotion in the morning whilst applying REKONAZOL cream in the evening. The mild steroid treatment can then be gradually stopped over a period of 2-3 weeks.

If you have any questions about stopping your steroid cream, ointment or lotion, ask your doctor or pharmacist.

Children and adolescents

REKONAZOL Cream is not recommended for use in children under 18 years of age.

Other medicines and REKONAZOL Cream

REKONAZOL cream does not normally react with other medicines. However, tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Pregnancy and breast-feeding

REKONAZOL cream can be used if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

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

REKONAZOL cream contains propylene glycol REKONAZOL cream contains cetyl alcohol and stearyl alcohol

This may cause skin irritation.

These may cause skin reactions such as contact dermatitis.

3. HOW TO TAKE REKONAZOL

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

How often you should use REKONAZOL cream

This will depend on the type of infection and how serious it is. Your doctor will tell you how often to use REKONAZOL cream and for how long. The recommended dose is:

- Once or twice each day for 1 to 6 weeks

Do not use the cream more often than your doctor has told you.

Preparing your skin

- Wash the infected skin and dry it well **Using REKONAZOL cream**
- Each tube of REKONAZOL 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 REKONAZOL cream in the eyes

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. REKONAZOL cream is non-greasy and should not stain clothes

If you stop using REKONAZOL cream

Keep using the cream for several days after all the symptoms have gone away. This will stop the symptoms from coming back.

If your symptoms do not improve after 4 weeks, talk to your doctor.

If you swallow REKONAZOL cream

If you swallow any cream, tell your doctor straight away.

If you have any further questions on the use of this product, 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 REKONAZOL cream and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Severe irritation or reddening of the skin where the cream has been used, or other signs of allergy during the first few days of treatment. This can affect fewer than 1 in 10 people
- Peeling or blistering of the skin. This can affect fewer than 1 in 100 people

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

Common side effects (affects fewer than 1 in 10 people)

- Burning sensation

Uncommon side effects (affects fewer than 1 in 100 people)

- Problems where the cream has been used such as:
- Bleeding
- Discomfort
- Dryness
- Inflammation (contact dermatitis)
- Tingling
- Rash, hives (also known as nettle rash or urticaria)
- Sticky skin

Reporting of side-effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 REKONAZOL

Keep 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 label. 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 REKONAZOL Cream contains

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

What REKONAZOL cream looks like and contents of the pack

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