

PACKAGE LEAFLET: INFORMATION FOR THE USER

REKONAZOL

2% shampoo

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% shampoo. It is called 'REKONAZOL Shampoo' or just 'shampoo' in this leaflet.

REKONAZOL shampoo contains a medicine called ketoconazole. This belongs to a group of medicines called 'antifungals'. Like other shampoos, it also contains ingredients to clean your hair.

REKONAZOL shampoo is used for fungal infections on the scalp and body such as:

- Dandruff
- Dry or greasy scaling of the scalp and other parts of the body called 'seborrhoeic dermatitis'
- White to brown patches on the body that sometimes appear after being in the sun called 'tinea versicolor' or 'pityriasis versicolor'

These conditions can be itchy. They are caused by a fungus (yeast) called '*Malassezia*'. This fungus is found on everyone's skin, but sometimes it can overgrow and cause problems. REKONAZOL shampoo works by killing the fungus and stopping it from coming back.

2. BEFORE YOU TAKE REKONAZOL

Do not use REKONAZOL shampoo if:

- You are allergic to anything in REKONAZOL shampoo

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 shampoo.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine:

- If you use a lotion or cream on your hair that contains a steroid, such as betamethasone or hydrocortisone:
- You should use less and less of the lotion or cream during the first 2 to 3 weeks of REKONAZOL shampoo treatment
- This will stop your condition flaring up while REKONAZOL shampoo starts to work

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

Children and adolescents

REKONAZOL Shampoo is not recommended for use in infants and children.

Other medicines and REKONAZOL Shampoo

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

3. HOW TO TAKE REKONAZOL

Always use this medicine exactly as your doctor has told you. REKONAZOL shampoo is for use on your hair or skin only. Check with your doctor or pharmacist if you are not sure.

How often you should use REKONAZOL shampoo The recommended dose is:

For dandruff or dry or greasy scaling of the skin

- Start by using the shampoo twice a week
- You should use it every 3 or 4 days for 2 to 4 weeks
- You should then use the shampoo once every 1 to 2 weeks to stop the symptoms coming back
- Do not use the shampoo more often than your doctor has told you

For white to brown patches on the skin

- You should use the shampoo on the white to brown patches of skin once a day for up to 5 days
- If the white to brown patches become more noticeable when you have been in the sun:
- You should use the shampoo once a day for 3 days before you next expose your skin to the sun
- Do not use the shampoo more often than your doctor has told you

Using REKONAZOL shampoo

- Wash your hair or infected part of skin with the shampoo
- Leave it on for 3 to 5 minutes
- Rinse thoroughly

If REKONAZOL shampoo gets in your eyes Gently bathe your eyes in cold water.

Using your normal shampoo

- If you need to wash your hair between treatments, use a normal shampoo
- If your hair is very thick or long, you can wash it with your usual shampoo and then use REKONAZOL shampoo **If you swallow REKONAZOL shampoo**

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

If you forget to use REKONAZOL shampoo

- If you miss a treatment with REKONAZOL shampoo, you should use it as soon as you remember
- Do not use the shampoo twice to make up for a missed treatment

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 shampoo and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Allergic reaction, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. This can affect fewer than 1 in 1000 people
- Severe irritation or reddening of the skin where the shampoo has been used, or other signs of allergy during the first few days of treatment.

This can affect fewer than 1 in 100 people

- Peeling or blistering of the skin. This can affect fewer than 1 in 1000 people

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

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

- Infection of the hair roots
- Increase in production of tears
- Unusual hair loss or thinning
- Dry skin, rash, burning feeling
- Changes in how your hair feels

Rare side effects (affects fewer than 1 in 1000 people)

- Taste impairment
- Irritation of the eyes
- Acne
- Flaking skin

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is classed as unknown

- Hives (also known as nettle rash or urticaria)
- Hair colour changes

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.

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 Shampoo contains

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

What REKONAZOL shampoo looks like and contents of the pack

REKONAZOL shampoo comes in a bottle containing 120 ml of shampoo.