

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ketoconazole 20 mg/g shampoo Ketoconazole

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 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 the 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 Ketoconazole shampoo is and what it is used for
2. What you need to know before you use Ketoconazole shampoo
3. How to use Ketoconazole shampoo
4. Possible side effects
5. How to store Ketoconazole shampoo
6. Contents of the pack and other information

1 What Ketoconazole shampoo is and what it is used for

Ketoconazole shampoo is a clear and reddish solution for shampooing.

Ketoconazole is used to treat **fungal infections** caused for example by yeast fungi, on **greasy, reddish, inflamed scalp** in adults and adolescents.

2 What you need to know before you use Ketoconazole shampoo

Do not use Ketoconazole shampoo

- if you are **allergic** to **ketoconazole** or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Ketoconazole shampoo.

If cortisone ointments, such as betamethasone or hydrocortisone, are being used

- on the same area,
- for a long period and
- you decide to stop this treatment:

Reduce the cortisone therapy gradually over 2-3 weeks while also using Ketoconazole.

Other medicines and Ketoconazole shampoo

No interactions with other medicines are known.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy and breast-feeding

There are no risks known for the use of ketoconazole shampoo in pregnancy or lactation.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Ketoconazole shampoo has no influence on the ability to drive or use machines.

3 How to use Ketoconazole shampoo

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

The recommended dose is for:

Adults and adolescents:

Fungal infections in the scalp:

Wash the infected area with the shampoo and rinse after 3-5 minutes.

Treatment: Twice weekly for 2-4 weeks.

Preventive treatment: Once weekly or once every second week.

If Ketoconazole shampoo gets in your eyes

Gently bathe your eyes in cold water.

If you swallow Ketoconazole shampoo

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

If you forget to use Ketoconazole shampoo

- If you miss a treatment with Ketoconazole 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 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 Ketoconazole shampoo and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

Uncommon (may affect up to 1 in 100 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.

Rare (may affect up to 1 in 1,000 people)

- Allergic reaction, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Peeling or blistering of the skin.

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

Uncommon (may affect up to 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 (may affect up to 1 in 1,000 people)

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

Not known (frequency cannot be estimated from the available data):

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Ketoconazole shampoo

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

Do not store above 25° C.

Do not use Ketoconazole shampoo after the expiry date which is stated on the packaging. 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 Contents of the pack and other information

What Ketoconazole shampoo contains

- The **active substance is ketoconazole**. 1 g of shampoo contains 20 mg ketoconazole (2%)

- The other ingredients are sodium lauryl ether sulphate, disodium monolauryl ether sulphosuccinate, macrogol 120 methyl glucose dioleate, macrogol 7 glyceryl cocoate, imidurea, laurdimonium hydroxypropyl hydrolysed animal collagen, coconut fatty acid diethanolamide, sodium hydroxide, sodium chloride, Ponceau 4 R (E124), hydrochloric acid, concentrated, purified water.

What Ketoconazole shampoo looks like and contents of the pack

Ketoconazole shampoo is a clear, reddish solution.

Pack sizes: 60 ml and 120 ml.

Marketing Authorisation Holder

Hexal AG
Industriestrasse 25
83607 Holzkirchen
Germany

Manufacturer

Next Pharma Pharbil Waltrop GmbH
Im Wirrigen 25
45731 Waltrop
Germany

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