



Package leaflet: Information for the patient

Ketozaz 2% 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 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 Ketozaz shampoo is and what it is used for
2. What you need to know before you use Ketozaz shampoo
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1. What Ketozaz shampoo is and what it is used for

Ketozaz 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. Ketozaz 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' (formerly known as Pityrosporum). This fungus is found on everyone's skin, but sometimes it can overgrow and cause problems. Ketozaz shampoo works by killing the fungus and stopping it from coming back.

2. What you need to know before you use Ketozaz shampoo

Do not use Ketozaz shampoo

If you are allergic (hypersensitivity) to ketoconazole, or to any drug containing an imidazole derivative, or to any of the other ingredients (listed in section 6).

If this applies to you, do not use Ketozaz shampoo and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

Take special care with Ketozaz shampoo:

- 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 Ketozaz shampoo treatment. This will stop your condition flaring up while Ketozaz shampoo starts to work.

If this applies to you, talk to your doctor or pharmacist.

Pregnancy and breast-feeding

Ketozaz shampoo can be used if you are pregnant or breast-feeding. However, ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Using Ketozaz shampoo will not affect your ability to drive or use machines.

3. How to use Ketozaz shampoo

Always use Ketozaz shampoo exactly as your doctor has told you. Ketozaz shampoo is for use on your hair or skin only. You should check with your doctor or pharmacist if you are not sure.

How often you should use Ketozaz shampoo

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 Ketozaz shampoo

- Wash your hair or infected part of skin (e.g. trunk, face, scalp) with the shampoo. Make sure you wash the skin and not just the hair.
- Leave it on for 3 to 5 minutes.
- Rinse thoroughly.

If Ketozaz shampoo gets in your eyes

- Gently bathe your eyes in cold water.

Using your regular shampoo

- If you need to wash your hair between treatments, use a regular shampoo.
- If your hair is very thick or long, you can wash it with your regular shampoo and then use Ketozaz shampoo.

If you swallow Ketozaz shampoo

If anyone swallows Ketozaz shampoo, contact a doctor or your nearest hospital taking this leaflet and pack with you.

If you forget to use Ketozaz shampoo

- If you miss a treatment with Ketozaz 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 Ketozaz 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.

Unknown frequency (frequency cannot be estimated from the available data): Hives (also known as nettle rash or urticaria), hair colour changes.

Reporting 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 Ketozaz shampoo

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use any Ketozaz shampoo if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Ketozaz shampoo contains

The active substances in Ketozaz shampoo is ketoconazole.

Ketozaz shampoo 2% contains 20 mg of ketoconazole in 1 g of shampoo.

The other ingredients are: purified water, citric acid, sodium hydroxide, sodium chloride, alkylamide propyl betaine, quaternized hydroxyethylcellulose, sodium lauryl ether sulfate, Euxyl K120, erythrosine sodium (E127), fragrance.

What Ketozaz shampoo looks like and contents of the pack

Ketozaz shampoo is a pink liquid shampoo. It is available in bottles of 100 ml.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in April 2022.

