

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ketozol Shampoo

Each 1 gram of shampoo contains:

Ketoconazole 20 mg

Inactive and allergenic ingredients in the preparation – see section 2 'Important information about some of the ingredients of the shampoo:' and section 6 'Further Information'.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ketozol Shampoo is intended for the treatment of seborrhoeic dermatitis and dandruff resulting from proven fungal infection, and for the treatment of pityriasis versicolor.

Therapeutic group:

Antifungal preparations.

Like other types of shampoo, the shampoo also contains ingredients to clean your hair.

The shampoo treats medical conditions that may be accompanied by itching. These conditions are caused by a fungus called *Malassezia*. This fungus is found on everyone's skin, but sometimes it can overgrow and cause problems. Ketozol Shampoo works by killing the fungus and preventing it from coming back.

2. BEFORE USING THE MEDICINE

Do not use Ketozol Shampoo if:

- You are sensitive (allergic) to the active ingredient ketoconazole or to any of the additional ingredients contained in the shampoo (see section 6 'Further Information').

Do not use Ketozol Shampoo if the above statement applies to you. If you are uncertain, speak to the doctor or pharmacist about it before using Ketozol Shampoo.

Special warnings regarding use of the medicine

Before treatment with Ketozol Shampoo, tell the doctor if:

- You use a lotion or cream on your hair that contains steroids, such as betamethasone or hydrocortisone:
 - Gradually reduce use of the lotion or cream during the first 2-3 weeks of treatment with Ketozol Shampoo.
- This will stop your medical condition from flaring up while Ketozol Shampoo starts to work.

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

Children and adolescents:

Ketozol Shampoo is intended for use in adults and children over 12 years of age.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or the pharmacist if you are using a cream or lotion containing steroids to treat the scalp (see section 'Special warnings regarding use of the medicine'). Ketozol Shampoo usually does not react with other medicines.

Pregnancy and breastfeeding:

The preparation can be used if you are pregnant or breastfeeding. If you are pregnant or breastfeeding, consult with the doctor or pharmacist before using any medicine.

Important information about some of the ingredients of the shampoo:

The shampoo contains Standapol ES-2 (sodium lauryl ether sulfate) which may cause localized skin reactions (e.g., a tingling or burning sensation) or increase the skin reactions to other agents being used on the same area.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

Ketozol Shampoo is intended for use in adults and children over 12 years of age.

The frequency of use of Ketozol Shampoo depends on the type of infection:

The usual dosage is generally:

Seborrhoeic dermatitis and dandruff: Use the shampoo twice a week for 2 to 4 weeks.

Pityriasis versicolor: Use once a day, for 5 days. Wash and lather the affected skin or scalp with Ketozol Shampoo and wait for 3-5 minutes before rinsing. Make sure you thoroughly lather the skin itself and scalp and not just the hair. Usually, using a palmful of Ketozol Shampoo is sufficient for one use.

As with other shampoo preparations, avoid contact with the eyes.

If the shampoo comes into contact with the eye area, wash the eyes with water.

Do not exceed the recommended dose.

For external use only.

Do not swallow Ketozol Shampoo. If you accidentally swallowed the preparation, refer to a doctor.

If you or your child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to use this preparation at the required time, do not use a double dose. Use the next dose at the usual time and consult a doctor.

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ketozol Shampoo may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using Ketozol Shampoo and refer to a doctor immediately if you notice or suspect any of the following effects. You may need urgent medical treatment.

Effects that can occur in less than one user in 1,000:

- Allergic reaction, swelling of the face, lips, mouth, tongue or neck, which may cause difficulty in swallowing or breathing

- Peeling of the skin or blisters

Effects that can occur in less than one user in 100:

- Severe irritation or redness of the skin where the shampoo was used, or other signs of allergy during the first days of the treatment

Effects that can occur in less than one user in 1,000:

- Peeling of the skin or blisters

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

Uncommon side effects (occur in up to one in 100 users):

- Inflammation of the hair roots
- Increased tear production
- Unusual hair loss or thinning
- Dry skin, rash, burning feeling
- Changes in the way your hair feels

Rare side effects (occur in up to one user in 1,000):

- Impaired sense of taste
- Eye irritation
- Acne
- Skin peeling

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Urticaria (allergic reaction)
- Change in hair color

If a side effect occurs, if one of the side effects worsens, or if you suffer from side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

In addition, you can report to Perrigo via the following address:

www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the bottle. The expiry date refers to the last day of that month.

- Do not store at a temperature above 25°C. Protect from light.

- After first opening the bottle, use within 4 weeks.

6. FURTHER INFORMATION

In addition to the active ingredient, the shampoo also contains:

Standapol ES-2 (Sodium Lauryl Ether Sulfate), Stepan-Mild SL-3 (Disodium Laureth Sulfosuccinate), Incomride CA (Coconut Fatty Acid Diethanolamide), Croquate L (Laurdimonium Hydroxypropyl Hydrolyzed Collagen), Sodium Chloride USP, Glucamate DOE-120 (PEG-120 Methyl Glucose Dioleate), Hydrochloric Acid NF, Sodium Hydroxide NF, Germall 115 (Imidurea NF), FD&C Red #40, Purified Water USP.

The shampoo contains 380 mg sodium lauryl ether sulfate in each 1 gram of shampoo.

What the preparation looks like and the contents of the package:

Ketozol Shampoo is a viscous orange-red fluid packaged in a white plastic bottle of 120 ml.

Registration holder and manufacturer: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.

Revised in September 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 13873.31583