

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

The medicine is dispensed with a doctor's prescription only

Nizoral® Cream

Composition and strength:
Ketoconazole 20 mg/gr

Inactive ingredients and allergens in the preparation - see section 6 "Further Information".

Read this 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 for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Nizoral Cream is not intended for use in children and adolescents under 18 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For the treatment of fungal infections of the skin and seborrheic dermatitis.

Therapeutic group:

An antifungal preparation from the imidazole group.

2. BEFORE USING THE MEDICINE:

⚠ Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient ketoconazole or to any of the other ingredients contained in the medicine.

Signs of hypersensitivity include itching and redness of the skin which can occur after applying the cream.

- For the list of additional ingredients, see section 6 "Further Information".

Special warnings regarding use of the medicine:

- Do not apply the cream to the eyes!
- If you are sensitive to any food or medicine, inform the doctor before using this medicine.
- Wash your hands after applying the cream.

⚠ If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Corticosteroid cream, ointment or lotion for topical use. If you are using such a preparation, consult with the doctor or pharmacist before commencing treatment with Nizoral Cream.

You can begin concomitant use of Nizoral Cream, but do not stop using a corticosteroid abruptly since this may cause a reaction of itching and reddening of the skin. In order to prevent this, for one week use the corticosteroid during the day and Nizoral Cream in the evening. Afterwards, apply the corticosteroid in the morning every two or three days and Nizoral Cream in the evening for 1-2 weeks. Then, the corticosteroid treatment can be stopped and treatment with Nizoral Cream can be continued, as needed.

Nizoral Cream is not intended for use in children and adolescents under 18 years of age.

⚠ Pregnancy and breastfeeding

The preparation can be used during pregnancy and when breastfeeding if the doctor has so instructed. There are no known risks regarding use of Nizoral Cream during pregnancy or when breastfeeding.

⚠ Driving and use of machinery

It is unlikely that Nizoral Cream will affect your ability to drive or operate machinery.

3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

The recommended dosage is application of the cream once or twice a day, as per the doctor's instructions.

The treatment is generally for 2-6 weeks, depending on the type of infection and on its severity.

Generally, you will see signs of improvement after 4 weeks.

Continue treatment for a few days after all the symptoms have disappeared.

Do not exceed the recommended dose.

For external use only. Do not swallow Nizoral Cream.

Avoid contact with the eyes and mucous membranes.

Wash your hands thoroughly after use.

To open the tube, unscrew the cap and pierce the sealed opening of the tube using the pin on the top of the cap.

Wash the treated area and dry it well before the treatment.

Apply enough Nizoral Cream to cover the affected area and surrounding skin, and rub in gently with your finger tips.

Wash your hands after completing each application of the cream. This is particularly important in order to prevent spreading the infection from the affected area to other parts of the body or to other people.

Be sure to have a towel and blanket for your own personal use only; this will prevent infecting others. Be sure to regularly change the clothing that comes into contact with the affected area, to prevent reinfection.

Complete the treatment recommended by the doctor. Antifungal treatments can be prolonged.

If a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a doctor!

How can you contribute to the success of the treatment

Moisture enhances fungal growth. Therefore, keep the affected area dry.

Wash the affected area before each application of the medicine. Between treatments with the cream - antifungal powder can be used to dry the area.

If the treatment is for the feet - take care to thoroughly wash and dry them, especially between the toes. It is advisable to wear cotton socks; avoid wearing socks made from wool or from synthetic materials. It is advisable to change them a few times a day (in accordance with the amount of sweat).

In the appropriate seasons, it is recommended to wear sandals without socks.

Do not take medicines in the dark! Check the label and 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 Nizoral Cream may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using the medicine and refer to a doctor immediately if you experience the following side effects. You may need urgent medical attention:

Common: Acute irritation of the skin or reddening of the skin in the area treated with the cream, or other signs of allergy during the first few days of use (e.g., rash, local eczema, irritation or local skin reactions).

Uncommon: peeling or blistering of the skin.

Tell the doctor or pharmacist if you experience the following side effects:

Common side effects - burning sensation

Uncommon side effects - bleeding, discomfort, dryness, contact dermatitis, tingling sensation, rash, urticaria (a skin disease), sticky skin

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

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

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

- The cream can be used for 6 months after first opening the tube.

- Store Nizoral Cream at a temperature between 15-30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, Nizoral Cream also contains:

Propylene glycol, stearyl alcohol, cetyl alcohol, sorbitan stearate, polysorbate 60, isopropyl myristate, 2 mg sodium sulphite anhydrous, polysorbate 80, purified water.

What does the medicine look like and what are the contents of the package

- A homogenous white cream
- Nizoral Cream is provided in a carton package with a 15 gram tube

License holder and address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer and address: Janssen Pharmaceutica, Beerse, Belgium.

This leaflet was checked and approved by the Ministry of Health in: 10/2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 042-19-25862-00