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

The medicine is dispensed with a doctor's prescription only

Nizoral® Cream

Active ingredient and its concentration
ketoconazole 20 mg/gr

Inactive and allergenic ingredients in the preparation – see in section 2 "Important information about some of the ingredients of the medicine" and 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of fungal infections of the skin, cutaneous candidosis, tinea versicolor and seborrheic dermatitis.

Therapeutic group:
An antifungal preparation from the imidazole group.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to the active ingredient ketoconazole or to any of the additional ingredients contained in the medicine. For the list of additional ingredients, see section 6 "Further information".
- To treat eye inflammations.

Do not use this medicine if any of the above apply to your condition. If you are not sure, consult the doctor or pharmacist before using the medicine.

Special warnings regarding use of the medicine
Before using Nizoral Cream, tell the doctor if

- You recently used a cream, ointment or lotion containing steroids on your skin infection
- Continue applying a mild steroid (such as hydrocortisone) cream, ointment or lotion in the morning whilst applying Nizoral Cream in the evening. The mild steroid treatment can then be gradually stopped over a period of 2-3 weeks.

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

Children and adolescents
Nizoral Cream is not intended for use in children and adolescents under 18 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. Nizoral Cream does not normally react with other medicines.

Pregnancy and breastfeeding
Nizoral Cream can be used during pregnancy or when breastfeeding. Consult the doctor or pharmacist before taking any medicine if you are pregnant or breastfeeding.

Driving and using machinery
It is unlikely that Nizoral Cream will affect the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine
Nizoral Cream contains propylene glycol
The preparation contains 3,000 mg propylene glycol in a 15 gram tube of Nizoral Cream, which is equivalent to 200 mg/gram.

Nizoral Cream contains cetyl alcohol and stearyl alcohol
Cetyl alcohol and stearyl alcohol may cause localized skin reactions (e.g., contact dermatitis).

3. HOW SHOULD THE MEDICINE BE USED?

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

The recommended dosage is usually:
For skin infections of the abdominal area, groin, feet and hands - apply Nizoral Cream to the affected and immediate surrounding area once or twice a day. The doctor will tell you how often and for how long.
For skin infections with reddish brown patches and yellow or white scales (seborrheic dermatitis) - apply Nizoral Cream once or twice a day.
Skin infections will usually get better within 2-4 weeks.
The doctor will tell you how often to use Nizoral Cream and for how long. Do not use the cream more than instructed by your doctor. The treatment is generally for 2-6 weeks, depending on the type of infection and on its severity.

Do not exceed the recommended dosage.
For external use only. Do not swallow Nizoral Cream.

Preparing the skin
Wash the affected area and dry it well.

Using Nizoral Cream
Each tube of Nizoral Cream is sealed. To open the tube, pierce the opening of the tube with the cap.
- Rub enough Nizoral Cream to cover the affected area and the surrounding skin and gently massage with the tips of the fingers.
- Do not put Nizoral Cream in the eyes.

Personal hygiene
- Unless the affected skin is on your hands, wash your hands with soap and water after completing each application of the cream.

- Washing your hands after using the cream will stop the spread of the infection from the affected area to other parts of the body or to other people.
  Do not allow other people to use your towel or blanket. This will stop others from getting infected.
- Be sure to frequently change clothing that come into contact with the affected area. Nizoral Cream is non-greasy and should not stain clothes.

If you accidentally take a higher dosage
If you used more Nizoral Cream than needed, it may cause a burning sensation, redness or swelling. If this occurs, stop using Nizoral Cream straight away.
If you used an overdose or if a child 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.

If you stop using Nizoral Cream
You will usually see signs of improvement after 4 weeks. If you do not feel it – consult the doctor.
Continue treatment for a few days after all symptoms disappear.
Even after your skin fully heals, you will sometimes have to apply the cream once weekly or once per 2 weeks. This will prevent recurrence of symptoms.

If you swallow Nizoral Cream
If you swallow any cream, tell your doctor straight away.

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. May affect less than 1 in 10 users.
Uncommon: Peeling or blistering of the skin. May affect less than 1 in 100 users.

Tell the doctor or pharmacist if you experience the following side effects:
Common side effects – effects that occur in less than 1 in 10 users:
- Burning sensation

Uncommon side effects – effects that occur in less than 1 in 100 users:

- Problems in the area treated with the cream, such as:
  - Bleeding
  - Discomfort
  - Dryness
  - Contact dermatitis
  - Tingling sensation
- Rash, urticaria
- Sticky skin sensation

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.

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

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 and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an 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.
- **Storage conditions:** Store Nizoral Cream below 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, sodium sulfite, polysorbate 80, purified water.

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

- A homogenous white cream
- Nizoral Cream is available in a carton package containing a 15 gram tube.

Manufacturer's name and address:
Stada Arzneimittel AG, Stadastrasse 2-18, 61118 Bad-vilbel, Germany.

Registration Holder's name and address:
Devries & Co. Ltd., 32 Habarzel St., Tel Aviv.

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

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