

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

The medicine is dispensed with a doctor's prescription only

Nizoral® Shampoo

Each gram contains: Ketoconazole 20 mg
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 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.

The medicine is not recommended for infants and children under the age of 12.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For the treatment of seborrhoeic dermatitis and dandruff resulting from proven fungal infection and for treating pityriasis versicolor.

Therapeutic Group:

Antifungal preparations

2. BEFORE USING THE MEDICINE

⊗ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, ketoconazole, or any of the additional ingredients contained in the medicine.
- For a list of the additional ingredients, see section 6 "Further information".
- Signs of allergy include itching and redness, occurring after use.

Special warnings regarding use with the medicine:

As with other shampoo preparations, avoid contact with the eyes. In the event that shampoo comes into contact with the eye area, rinse the eyes with water.

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

Corticosteroids (medicines from the cortisone group) for use on the scalp in a cream, ointment or lotion. You may start using Nizoral Shampoo right away, but do not stop using preparations containing corticosteroids abruptly, since redness or itching may develop at the treated area. Discontinuation of corticosteroids use should be done gradually. Continue treatment with the same quantity of preparations containing corticosteroids for another week. Gradually reduce the frequency of use over a 1 to 2 weeks period. After that, you can stop use corticosteroids entirely.

If in doubt, consult your doctor or pharmacist.

⚠ Pregnancy and breastfeeding

Nizoral Shampoo can be used if you are pregnant and breast-feeding.

No risks are known with regards to use of Nizoral Shampoo during pregnancy or when breastfeeding.

3. HOW SHOULD YOU USE THE MEDICINE?

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

Frequency of use of Nizoral Shampoo depends on the type of infection:

For seborrhoeic dermatitis and dandruff:

Use the shampoo twice a week for two to four weeks.

For pityriasis versicolor, use once a day for 5 days.

Wash and soap the affected skin or scalp with Nizoral Shampoo and wait for 3 to 5 minutes before rinsing off. Make sure you thoroughly lather the skin itself and the scalp and not just the hair. Usually a palmful of Nizoral Shampoo suffices for one use.

As with other shampoo preparations, avoid contact with the eyes. In the event that shampoo comes into contact with the eye area, rinse the eyes with water.

Do not exceed the recommended dose.

For external use only. Do not swallow Nizoral Shampoo.

In the event that you accidentally swallowed the preparation, refer to a doctor.

If you accidentally swallowed Nizoral Shampoo, or if a 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.

Be sure to adhere to the treatment 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 a doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Nizoral 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 treatment with Nizoral Shampoo and refer to a doctor immediately in the event that you detect one of the following. It is possible that you will need immediate medical attention:

- Allergic reaction, swelling of the face, lips, mouth, tongue or throat that may cause problems with swallowing or breathing.

- 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.

- Peeling or blistering of the skin.

Additional side effects:

Uncommon side effects:

Infection of the hair follicles, increase in production of tears, hair loss or thinning of the hair, dry skin, skin rash, burning sensation on skin, changes in how your hair feels

Rare side effects:

Taste impairment, irritation of the eyes, acne, flaking skin

Side effects whose frequency is unknown:

Urticaria, changes in hair color

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

5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the 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 package. The expiry date refers to the last day of that month.

• The shampoo is good for use for 6 months after first opening the bottle.

• Store Nizoral Shampoo at a temperature below 25°C.

• Store the bottle properly closed.

6. FURTHER INFORMATION

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

Sodium lauryl ether sulphate, disodium monolauryl ether sulphosuccinate, coconut fatty acid diethanolamide, laurdimonium hydrolyzed animal collagen, macrogol 120 methyl glucose dioleate, perfume bouquet, imidurea, concentrated hydrochloric acid, erythrosine (E127), sodium chloride, sodium hydroxide, purified water.

What the medicine looks and the contents of the package

• A viscous and clear pink liquid with an herbal fragrance.

• Nizoral Shampoo comes in a carton box which contains a 100 ml bottle.

Registration 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 on June 4, 2015

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 107-01-26656-00