

NIZORAL® SHAMPOO

FOR EXTERNAL USE ONLY



WHAT IS NIZORAL SHAMPOO FOR?

Nizoral Shampoo is a medicine to treat and prevent the relapse of **skin infections caused by fungi or yeasts**. Both the scalp and larger areas on the chest or face can be treated with the shampoo. Nizoral Shampoo is not recommended for use in infants and children below the age of 12 years.

It is used for various skin infections, which you can recognize by:

- **scales on the scalp** (dandruff);
- **reddish brown patches** with yellow or white scaling, usually **in the face or on the chest** (seborrheic dermatitis);
- **small, brown or white-colored, irregular patches on the trunk** (pityriasis versicolor).



WHEN NOT TO USE NIZORAL SHAMPOO

Do not use Nizoral Shampoo if you know you are **hypersensitive (allergic)** to it.

Symptoms of hypersensitivity include itching and red skin, occurring after application.

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?

As with other shampoos, avoid contact with the eyes. If this happens, however, rinse the eyes with water.



Pregnancy and breast-feeding

You can use Nizoral Shampoo. There are no known risks with the use of Nizoral Shampoo in pregnancy or breast-feeding.



Other medicines

Corticosteroids (cortisone-type medicines) in cream, ointment or lotion.

If you are using such a medicine, check with your doctor or pharmacist before starting treatment with Nizoral Shampoo. You may start with Nizoral Shampoo right away, but do not stop using the corticosteroid from one day to the next. The skin might react by redness and itching.

Continue your corticosteroid treatment as follows:

- apply the same quantities for 1 week;
- gradually reduce the frequency over a further 1 to 2-week period;
- then stop using the corticosteroid entirely.

If in doubt, consult your doctor or pharmacist.



HOW TO USE NIZORAL SHAMPOO AND HOW MUCH

Wash the infected parts of the skin or scalp with Nizoral Shampoo and **allow the product to soak in for 3 to 5 minutes before rinsing.**

Make sure you thoroughly wash the skin or scalp itself and not just the hair. Usually a **palmful or 1 sachet of shampoo** suffices for one wash.

How often you will need to use Nizoral will depend on the type of infection and on whether you wish to cure or prevent it.

- Scales on the scalp (dandruff) and reddish brown patches with yellow or white scaling in the face or on the chest (seborrheic dermatitis).
 - For treatment, twice a week for 2 to 4 weeks.
 - To prevent relapses, once a week or once every 2 weeks.
- Small, brown or white-colored, irregular patches on the trunk (pityriasis versicolor)
 - For treatment, once a day for 1 to 3 days.



UNDESIRE EFFECTS

Application site reactions including collection of pus within the skin or hair follicles (pustules), shedding of skin, inflamed hair follicles, itching, irritation, skin burning sensation, red, dry or tender skin; rash; acne; hair loss or hair color or texture changes; and eye irritation or increase tearing may occur infrequently. Hypersensitivity (allergic) reactions: sudden swelling of the skin or mucous membranes usually of the face, eyes, or lips; hives; localized itchy skin rash (eczema); or distorted taste perception may also occur infrequently. In case you do not tolerate the shampoo, discontinue treatment.

Do not hesitate to report any undesired effects to your doctor or pharmacist.



OVERDOSE

Nizoral Shampoo should not be swallowed. If Nizoral Shampoo is accidentally swallowed, contact your doctor.

Information for the doctor in case of overdose

In the event of accidental ingestion, only supportive and symptomatic measures should be employed.

In order to avoid aspiration, emesis or gastric lavage should not be performed.



HOW TO STORE NIZORAL SHAMPOO

Keep Nizoral Shampoo between 15°C and 25°C and always keep the bottle properly closed. This medicine can be kept for only a limited period. Do not use Nizoral Shampoo after the date (month and year) printed after “EXP”, even if it has been kept properly.

You are advised to return old medicines to your pharmacist.



WHAT IS IN NIZORAL SHAMPOO?

Nizoral Shampoo is a medicine for adults and adolescents to treat and prevent skin infections caused by fungi or yeasts.

The active ingredient in Nizoral Shampoo is ketoconazole.

Nizoral Shampoo comes in 100 and 60 millilitre bottles.

Nizoral Shampoo contains 20 milligrams of ketoconazole per gram.

The product also contains sodium laureth sulphate, disodium monolaureth sulphosuccinate, coconut fatty acid diethanolamide, laurdimonium hydrolyzed animal collagen, macrogol 120 methyl glucose dioleate, perfume bouquet, imidurea, hydrochloric acid, sodium hydroxide, erythrosine sodium, sodium chloride and purified water.

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What you should know about medicines...

Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.

It is important that you use medicines correctly. That is, you should:

- Always carefully read the full patient information leaflet;*
- Use medicines only for the purpose for which you were given the medicines;*
- Use medicines only in the prescribed amount;*
- Use medicines only for the prescribed period of time.*

Keep all medicines out of the reach of children.

Never allow others to use medicines recommended for you and never use medicines prescribed for others.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!)

Make a habit of returning unused or old medicines to your pharmacist.

If someone has taken an overdose of a medicine, call a doctor.

Please consult your doctor or pharmacist if you require more information.

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