

Package leaflet: Information for the user

Nizoral® 20mg/g Cream

ketoconazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Nizoral cream is and what it is used for
2. What you need to know before you use Nizoral Cream
3. How to use Nizoral Cream
4. Possible side effects
5. How to store Nizoral Cream
6. Contents of the pack and other information

1. What Nizoral cream is and what it is used for

Nizoral Cream is used to treat fungal infections of the skin which may appear on the hands, feet, genital area, trunk, groin, scalp, face, chest or back. These can be caused by a variety of fungi or yeasts and Nizoral Cream works by destroying the fungus that causes the infection.

2. What you need to know before you use Nizoral Cream

This product is suitable for most adults, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not use this product

- If you have ever had an allergic (hypersensitivity) reaction to any of the ingredients.

If this applies to you, get advice from a doctor or pharmacist without using Nizoral Cream.

Pregnancy and breast-feeding

- You can use Nizoral Cream if you are pregnant, think you might be pregnant or are breast-feeding.

Take special care with Nizoral Cream

- If you have been regularly using a lotion or cream, which contains a steroid (such as *betamethasone* or *hydrocortisone*) to control your skin infection, you should wait for two weeks before starting treatment with Nizoral Cream. This will stop your condition flaring up while Nizoral Cream starts to work. If you have any questions about stopping your steroid lotion or cream, **speak to your doctor or pharmacist.**

Driving and using machines

Using Nizoral Cream will not affect your ability to drive or use machines.

Nizoral cream contains 200 mg propylene glycol in each gram of cream.

Propylene glycol may cause skin irritation.

Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns) without checking with your doctor or pharmacist.

3. How to use Nizoral cream

- Each tube of Nizoral Cream is sealed.
- For skin infections of the trunk, groin, feet and hands, apply Nizoral Cream to the affected and immediate surrounding area once or twice a day.
- Your doctor will tell you how often to use it and for how long. Depending on the type of skin infection, treatment may last 2 to 6 weeks.

The recommended dosage is:

For skin infections with reddish brown patches and yellow or white scaling (seborrheic dermatitis), apply Nizoral Cream once or twice a day. Skin infections will usually get better after 2 to 4 weeks.

Usually you will see signs of improvement after 4 weeks. If this is not the case, talk to your doctor.

Keep on using the cream until a few days after all symptoms have completely disappeared.

Even after your skin is completely cured, you sometimes have to apply the cream once weekly or once per 2 weeks. This prevents your symptoms from recurring.

Adults aged 18 years and over**Each time you use the cream:**

- Wash the infected skin and dry it well. As many skin conditions are infectious, you should keep a towel and a flannel for your own use so that you do not infect anyone else.
- Rub Nizoral Cream gently into the affected area and surrounding skin with clean fingers
- Unless the infected skin is on your hands, wash your hands carefully after applying the cream to avoid spreading the infection to other parts of the body or to other people. Similarly, clothing which comes into contact with the infected areas should be washed and changed frequently. Nizoral Cream is non-greasy and should not stain clothes.

If anyone accidentally swallows this product

If anyone accidentally swallows Nizoral Cream, contact a doctor or your nearest Accident & Emergency department (Casualty) taking this leaflet and pack with you.

If you forget an application

If you forget to use Nizoral Cream use as per the directions next time you apply the product.

4. Possible side effects

Nizoral Cream can have side-effects like all medicines, although these don't affect everyone and are usually mild.

Stop using Nizoral Cream and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Severe irritation or reddening of the skin where the cream has been used, or other signs of allergy during the first few days of treatment. This can affect fewer than 1 in 100 people
- Peeling or blistering of the skin. This can affect fewer than 1 in 100 people.

Effects which may occur include:

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

Common side effects (affects fewer than 1 in 10 people)

- Burning sensation
- Skin redness or itching

Uncommon side effects (affects fewer than 1 in 100 people)

- Hypersensitivity
- Bullous eruptions (raised blisters) or dermatitis contact (inflammation of the skin)
- Shedding of the skin
- Problems where the cream has been used such as:
 - Bleeding
 - Discomfort
 - Dryness
 - Inflammation at the site of application
 - Tingling
- Skin irritation such as rash (also known as nettle rash)
- Sticky skin

Not known (frequency of occurrence is not known)

- Urticaria (hives)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nizoral cream

Keep the product out of the reach and sight of children.

Do not store above 25°C.

Do not use this product after the expiry date shown on the packaging.

6. Contents of the pack and other information

What Nizoral cream contains

- **The active ingredient** in 1 g of Nizoral Cream is ketoconazole 20 mg.

- **Other ingredients are:** purified water, propylene glycol*, cetyl alcohol* and stearyl alcohol*, sorbitan stearate, polysorbate 60 and 80, sodium sulphite (E221) and isopropyl myristate.

*may cause skin irritation (eg contact dermatitis)

What Nizoral cream looks like and contents of the pack

Nizoral Cream is a white cream and is supplied in tubes of 30g.

Marketing Authorisation Holder

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Manufacturer

Janssen Pharmaceutica N.V., Beerse, Belgium

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