

Nizoral® 20mg/g Cream

ketoconazole

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to use Nizoral Cream carefully to get the best results from it.

- * Keep this leaflet. You may need to read it again.
- * Ask your pharmacist if you need more information or advice.
- * You must contact a doctor if your symptoms worsen or do not improve.
- * If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

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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 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.

Important information about some of the ingredients of Nizoral Cream

- * Nizoral Cream contains propylene glycol, cetyl alcohol and stearyl alcohol which may cause skin irritation (eg contact dermatitis).

3 How to use Nizoral Cream

- * Each tube of Nizoral Cream is sealed.
- * For cutaneous use only, which means it is applied directly to the affected area of skin.
- * Do not use more than the stated dose.

Depending on the type of infection, treatment may last 2 to 6 weeks.

Apply Nizoral Cream to the affected and immediate surrounding area once or twice a day. Usually you will see signs of improvement after 4 weeks. If this is not the case, talk to your doctor. Keep using the cream until a few days after all symptoms have completely disappeared.

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. Depending on the type of skin infection, treatment may last 2 to 6 weeks.

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 the next dose when needed. Do not use a double dose.

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 via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Nizoral Cream

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Further information

What Nizoral cream contains:

The active ingredient is ketoconazole. Each gram of cream contains 20 mg of ketoconazole.

The other ingredients are: purified water, propylene glycol, cetyl alcohol, stearyl alcohol, sorbitan monostearate, polysorbate 60 and 80, sodium sulphite anhydrous (E 221), isopropyl myristate.

What Nizoral cream looks like and contents of the pack

Nizoral Cream is a white cream and is supplied in tubes of 15 g.

Parallel Product Authorisation Holder:

Lexon Pharmaceuticals (Ireland) Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

Repackaged by:

Lexon Pharmaceuticals (Ireland) Limited, Units 22 & 25, Block 4, Port Tunnel Business Park, Clonshaugh, Dublin 17, Ireland.

The manufacturer is:

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Blind or partially sighted?

Is this leaflet hard to see or read?

**Phone Lexon Pharmaceuticals (Ireland) Limited,
Tel: +35318710550 for help.**