

Patient Information leaflet

Nizoral® 2% Cream (ketoconazole)

Read all of this leaflet carefully before you start using this medicine.

- 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

The name of your medicine is Nizoral 2% Cream. It is called 'Nizoral Cream' or just 'cream' in this leaflet.

Nizoral Cream contains a medicine called ketoconazole. This belongs to a group of medicines called 'antifungals'.

Nizoral Cream is used for fungal and yeast infections of the skin in adults.

Infections may appear on the:

- Trunk, chest or back
- Hands or feet
- Scalp or face
- Groin or genitals

Nizoral Cream works by killing the fungus that causes the infection.

2) WHAT YOU NEED TO KNOW BEFORE YOU USE NIZORAL CREAM

Do not use Nizoral Cream:

- If you are allergic to anything in Nizoral Cream (listed in section 6 below)
- For eye infections

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Nizoral Cream.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine:

- If you have recently used a cream, ointment or lotion on your skin infection that contains a steroid:
 - You should continue to apply 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, ask your doctor or pharmacist.

Children and adolescents

Nizoral Cream is not recommended for use in children under 18 years of age.

Other medicines and Nizoral Cream

Nizoral Cream does not normally react with other medicines. However, tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Pregnancy and breast-feeding

Nizoral Cream can be used if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Nizoral Cream is not likely to affect you being able to drive or use any tools or machines.

Nizoral Cream contains propylene glycol

This medicine contains 6000 mg propylene glycol in each 30 g tube, which is equivalent to 200 mg/g.

Nizoral Cream contains cetyl alcohol and stearyl alcohol

Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3) HOW TO USE NIZORAL CREAM

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How often you should use Nizoral Cream

Your doctor will tell you how often to use Nizoral cream and for how long.

The recommended dose is:

- 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.
- 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.

Your doctor will tell you how often to use Nizoral Cream and for how long. Do not use the cream more often than your doctor has told you. Depending on the type of infection, treatment may last 2 to 6 weeks.

Preparing your skin

- Wash the infected skin and dry it well

Using Nizoral Cream

- Each tube of Nizoral Cream is sealed. You will need to use the cap to pierce the seal
- Rub the cream gently into the affected area and surrounding skin with clean 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 using the cream
- Washing your hands after using the cream will stop you spreading the infection to other parts of your body or to other people
- Do not allow other people to use your flannel or towel. This will stop them from getting your infection
- Clothing that touches infected skin should be washed and changed often. Nizoral Cream is non-greasy and should not stain clothes

If you stop using Nizoral Cream

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.

If you swallow Nizoral Cream

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

If you use Nizoral Cream more often than you should

If you use Nizoral Cream more often than you should, it may cause some burning sensation, redness or swelling. If this occurs, stop using Nizoral Cream straight away.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4) POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 10 people
- Peeling or blistering of the skin. This can affect fewer than 1 in 100 people

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

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

- Problems where the cream has been used such as:
 - Bleeding
 - Discomfort
 - Dryness
 - Inflammation (contact dermatitis)
 - Tingling
- Rash, hives (also known as nettle rash or urticaria)
- Sticky skin

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

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

5) HOW TO STORE NIZORAL CREAM

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original packaging.
- Do not use Nizoral Cream after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6) CONTENTS OF THE PACK AND OTHER INFORMATION

What Nizoral Cream contains

Each gram of cream contains 20mg of ketoconazole (2% w/w).

The other ingredients are propylene glycol, cetyl alcohol, stearyl alcohol, sorbitan monostearate, polysorbate 60, polysorbate 80, anhydrous sodium sulphite (E221), isopropyl myristate and purified water.

(See end of Section 2 for further information on propylene glycol, cetyl alcohol and stearyl alcohol).

What Nizoral Cream looks like and contents of the pack

Nizoral Cream comes in tubes containing 15g of white cream.

Pack sizes: 1 x 15g tube and 2 x 15g tubes.

Manufactured by

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

Procured from within the EU by the Product Licence Holder:

MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER.

Repackaged by MPT Pharma Ltd.

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Leaflet dated 28th May 2021

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To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.

Patient Information leaflet

Ketoconazole 2% Cream

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In this leaflet

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

1) WHAT KETOCONAZOLE CREAM IS AND WHAT IT IS USED FOR

The name of your medicine is Ketoconazole 2% Cream. It is called 'Ketoconazole Cream' or just 'cream' in this leaflet.

Ketoconazole Cream contains a medicine called ketoconazole. This belongs to a group of medicines called 'antifungals'.

Ketoconazole Cream is used for fungal and yeast infections of the skin in adults.

Infections may appear on the:

- Trunk, chest or back
- Hands or feet
- Scalp or face
- Groin or genitals

Ketoconazole Cream works by killing the fungus that causes the infection.

2) WHAT YOU NEED TO KNOW BEFORE YOU USE KETOCONAZOLE CREAM

Do not use Ketoconazole Cream:

- If you are allergic to anything in Ketoconazole Cream (listed in section 6 below)
- For eye infections

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Ketoconazole Cream.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine:

- If you have recently used a cream, ointment or lotion on your skin infection that contains a steroid:
 - You should continue to apply a mild steroid (such as hydrocortisone) cream, ointment or lotion in the morning whilst applying Ketoconazole 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, ask your doctor or pharmacist.

Children and adolescents

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Other medicines and Ketoconazole Cream

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Ketoconazole Cream contains propylene glycol

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Ketoconazole Cream contains cetyl alcohol and stearyl alcohol

Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3) HOW TO USE KETOCONAZOLE CREAM

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How often you should use Ketoconazole Cream

Your doctor will tell you how often to use Ketoconazole cream and for how long.

The recommended dose is:

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Preparing your skin

- Wash the infected skin and dry it well

Using Ketoconazole Cream

- Each tube of Ketoconazole Cream is sealed. You will need to use the cap to pierce the seal
- Rub the cream gently into the affected area and surrounding skin with clean fingers
- Do not put Ketoconazole Cream in the eyes

Personal hygiene

- Unless the affected skin is on your hands, wash your hands with soap and water after using the cream
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