

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nizoral[®] 2% cream

Ketoconazole

Nizoral is a registered trademark

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

1. What Nizoral cream is and what it is used for
2. Before you use Nizoral cream
3. How to use Nizoral cream
4. Possible side effects
5. How to store Nizoral cream
6. Further 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. 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. 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.

Take special care with Nizoral cream

Check with 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.

Taking other medicines

Nizoral cream does not normally react with other medicines. However, please 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.

But 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.

Important information about some of the ingredients of Nizoral cream

- Nizoral cream contains propylene glycol. This may cause skin irritation
- Nizoral cream also contains cetyl alcohol and stearyl alcohol. These may cause skin reactions such as contact dermatitis

3. How to use Nizoral cream

Always use Nizoral cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How often you should use Nizoral cream

This will depend on the type of infection and how serious it is. Your doctor will tell you how often to use Nizoral cream and for how long.

The cream is normally used:

- Once or twice each day for 1 to 6 weeks

Do not use the cream more often than your doctor has told you.

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

When to stop using Nizoral cream

Keep using the cream for several days after all the symptoms have gone away. This will stop the symptoms from coming back.

If your symptoms do not improve after 4 weeks, talk to your doctor.

If you swallow Nizoral cream

If you swallow any cream, tell your doctor 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, Nizoral cream 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

5. How to store Nizoral cream

Keep out of the reach and sight of children.

Store the cream in its original packaging. Do not store above 25°C.

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.

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 protect the environment.

6. Further information

The active substance in Nizoral cream is ketoconazole. Each gram (g) of Nizoral cream contains 20 milligrams (mg) of ketoconazole (2 % w/w).

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

What Nizoral cream looks like and contents of the pack

Nizoral cream comes in a tube containing 30 g of white cream.

The product licence is held by:

JANSSEN-CILAG LTD, 50 –100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

Nizoral cream is made by:

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

OR

McGregor Cory Ltd, Exel, Middleton Close, Banbury, OX16 4RS, UK

For information in large print, tape, CD or Braille, telephone 0800 7318450.

This leaflet was last approved in June 2011.