

NIZORAL[®] (ketoconazole)

Cream (For external use only)

Before you start to take your medicine, please read this leaflet carefully all the way through as it contains important information. If there is anything that you do not understand or if you need further information or advice, you should ask your doctor or pharmacist who will be pleased to help you. Please do not throw this leaflet away until you have finished taking the full course of your medicine. You may need to refer to it again.



WHAT IS NIZORAL[®] CREAM FOR?

NIZORAL[®] Cream is a medicine for treating **skin infections** caused by fungi or yeasts.

It is used for treating skin infections on the **trunk, groin, feet or hands**. NIZORAL[®] Cream is also used to treat skin infections that usually occur on the **face** and on **the chest** with reddish brown patches and yellow or white scaling (seborrheic dermatitis).



WHEN NOT TO USE NIZORAL[®] CREAM

Do not use NIZORAL[®] Cream if you know you are **hypersensitive** (allergic) to it. Symptoms of hypersensitivity include itching and red skin which may occur after you have applied NIZORAL[®] Cream.

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?

Do not apply NIZORAL[®] Cream to the eyes.

Wash your hands carefully after you have applied NIZORAL[®] Cream.



Pregnancy and breast-feeding

There are no known risks with the use of NIZORAL[®] Cream in pregnancy or breast-feeding.



Other medicines

If you are also using corticosteroids (cortisone-type medicines in cream, ointment or lotion), check with your doctor or pharmacist before starting treatment with NIZORAL[®] Cream.



HOW TO USE NIZORAL[®] CREAM AND HOW MUCH

You should apply NIZORAL[®] Cream once or twice a day as instructed by your doctor. Depending on the type of infection, treatment may last 2 to 6 weeks. Usually you will see signs of improvement after 4 weeks. If this is not the case, talk to your doctor.

Do not stop using the cream until a few days after all symptoms have completely disappeared.

- To open the tube, unscrew the cap and then pierce the seal of the tube using the pin on the top of the cap.
- Wash the infected skin and dry it well.
- Rub NIZORAL[®] Cream gently into the infected area and the area around the infected area with your fingertips.
- Wash your hands carefully after you have used NIZORAL[®] Cream, except if the treatment is for the hands.

For skin infections of the **trunk, groin, feet and hands**, apply NIZORAL[®] Cream **once a day**.

For skin infections that usually occur on the **face** and on the **chest** 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 and after that you can continue to use NIZORAL[®] once or twice a week.

Keep a separate towel and flannel for your own use to avoid infecting other people. Change clothing which comes into contact with the infected skin regularly to avoid re-infecting yourself.



UNDESIRE EFFECTS

Like all medicines, NIZORAL[®] can cause side effects, although not everybody gets them. Tell your doctor if you notice any of the following side effects while using NIZORAL[®]:

- Skin burning sensation, itching or redness
- Hyper-sensitivity (allergic) reactions, rashes, eczema, hives, irritation or other local skin reactions

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



OVERDOSE

When too much NIZORAL[®] Cream is applied or NIZORAL[®] Cream is applied more frequently than instructed by your doctor, it may cause some burning sensation, redness or swelling. If this happens, stop using NIZORAL[®] straight away.

NIZORAL[®] Cream should not be swallowed. If NIZORAL[®] Cream is accidentally swallowed, contact your doctor.



HOW TO STORE NIZORAL[®] CREAM

Do not use NIZORAL[®] Cream after the date (month and year) printed after "EXP", even if it has been stored properly. Return old medicines to your pharmacist.

Store between 15°C and 30°C. Protect from light.



WHAT IS IN NIZORAL[®] CREAM?

NIZORAL[®] Cream is a medicine for treating skin infections caused by fungi or yeasts.

The active ingredient in NIZORAL[®] Cream is **ketoconazole**.

NIZORAL[®] 2% Cream is supplied in tubes of 15 g. Each gram contains 20 mg ketoconazole.

NIZORAL[®] Cream also contains cetyl alcohol, isopropyl myristate, polysorbate, propylene glycol, sodium sulfite, sorbitan stearate, stearyl alcohol and water.

Batch Releaser:

Janssen Pharmaceutica NV.

Turnhoutseweg 30

B-2340 Beerse Belgium

Product Registrant:

Johnson & Johnson International (Singapore) Pte. Ltd.

2 Science Park Drive

#07-13, Ascent

Singapore Science Park 1

Singapore 118222

Latest update of this package insert:

30 January 2023 (CPPI 04 October 2017)

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!).

Return unused or old medicines to your pharmacist.

If someone has taken an overdose of a medicine, call a doctor or the poison control centre.