

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nizoral[®] 200 mg tablets

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 tablets are and what they are used for
2. Before you take Nizoral tablets
3. How to take Nizoral tablets
4. Possible side effects
5. How to store Nizoral tablets
6. Further information

1. What Nizoral tablets are and what they are used for

The name of your medicine is Nizoral 200 mg tablets. They are called 'Nizoral tablets' in this leaflet.

Nizoral tablets contain a medicine called ketoconazole. This belongs to a group of medicines called 'antifungals'.

Nizoral tablets are used to treat a range of conditions which can't be treated with other antifungal medicines, including some fungal infections affecting the skin, mouth and throat.

Nizoral tablets work by killing the fungus that causes the infection.

2. Before you take Nizoral tablets

Do not take Nizoral tablets:

- If you are allergic to anything in Nizoral tablets (listed in section 6 below)
- If you are allergic to 'antifungal' medicines called 'imidazoles'
- If you have ever had liver problems
You **must** inform your doctor of any previous **liver disease**
- In children weighing less than 15 kg

Do not take this medicine if any of the above apply to you or your child. If you are not sure, talk to your doctor or pharmacist before using Nizoral tablets.

Liver problems

Liver problems can sometimes happen, even with a short course of Nizoral tablets.

If after taking this medicine you:

- Have long-lasting severe headache or blurred vision
- Have a severe lack of appetite
- Lose a large amount of weight (anorexia)
- Feel sick (nausea) or are sick (vomiting)
- Feel unusually tired or feverish
- Get stomach pain
- Have muscle weakness
- Get yellowing of the skin or whites of the eyes
- Pass unusually dark urine or pale stools

Stop taking Nizoral tablets and tell your doctor straight away.

Blood tests

Before you are given Nizoral tablets your doctor will check your liver by testing your blood. Your doctor will then re-test your blood at weeks 2 and 4 of your treatment. If your treatment continues longer than this, your doctor will continue to re-test your blood every 4 weeks.

Adrenal gland problems

The adrenal glands are involved in the response to stress. Tell your doctor if:

- You have Addison's disease (adrenal glands not working properly)
- You are under periods of stress, such as facing major surgery

Your doctor may need to check how your adrenal glands are working.

Taking other medicines

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.

Do not take Nizoral tablets and tell your doctor if you are taking any of the following medicines:

- Terfenadine, astemizole or mizolastine for hayfever or allergy.
- Halofantrine, a medicine used to treat malaria
- Levacetylmethadol (levomethadyl), a medicine for severe pain or to manage addiction
- Lovastatin or simvastatin to lower cholesterol
- Quinidine, disopyramide or dofetilide for an irregular heart beat
- Midazolam (by mouth) or triazolam for anxiety or to help you sleep
- Cisapride for digestive problems
- Pimozide or sertindole for conditions affecting thoughts, feelings and behaviour
- Nisoldipine and bepridil for angina (crushing chest pain) and high blood pressure
- Eplerenone for heart failure
- Ergot alkaloids:
 - Ergometrine (ergonovine) or methylergometrine (methylergonovine) after childbirth
 - Ergotamine for migraine
- Irinotecan, an anti-cancer drug
- Everolimus, usually given after an organ transplant and sirolimus (also known as rapamycin)

Do not start taking Nizoral tablets and tell your doctor if you are taking any of the above.

You must talk to your doctor before taking Nizoral tablets if you take:

- Domperidone, a medicine used to avoid feeling sick

Your doctor may need to alter the dose of Nizoral tablets or certain other medicines if you take them together

Tell your doctor if you are taking:

- Medicines to thin the blood such as warfarin
- Medicines that are usually given after an organ transplant called ciclosporin, busulphan and tacrolimus
- Medicines for inflammation (given by mouth, injection or inhaled) called methylprednisolone, budesonide, fluticasone or dexamethasone
- Medicines that act on the heart and blood vessels called digoxin, or 'calcium-channel blockers' such as dihydropyridines or verapamil
- Medicines for pain called alfentanil or fentanyl
- Medicines used in the treatment of cancer such as docetaxel and a group of medicines known as 'vinca alkaloids'
- Medicines for HIV infection such as:
 - Indinavir and saquinavir (antiviral protease inhibitors)
 - Nevirapine (a non-nucleoside reverse transcriptase inhibitor)
 - Ritonavir. Your doctor may have to lower your dose of Nizoral tablets if you are taking this medicine
- Medicines for anxiety or to help you sleep (tranquillisers) such as buspirone, alprazolam or brotizolam
- Medicines used in the treatment of cancer including erlotinib and imatinib
- Midazolam to help you relax or sleep when given into a vein
- Sildenafil for impotence (erectile dysfunction)
- A medicine called trimetrexate used for a certain type of pneumonia
- Ebastine for allergy
- Medicines for epilepsy called phenytoin or carbamazepine
- Rifampicin for serious bacterial infections
- Medicines for tuberculosis called isoniazid or rifabutin
- Atorvastatin to lower cholesterol
- Reboxetine for depression
- Cilostazol to help circulation
- Repaglinide for diabetes
- Eletriptan for migraine headaches
- Quetiapine, used to treat conditions affecting thoughts, feelings or behaviours
- Medicines called tolterodine and solifenacin used to help control the need to urinate too often

Talk to your doctor before taking Nizoral tablets if you are taking any of these medicines.

Taking Nizoral tablets with food

Always take Nizoral tablets with food as this helps your body to use the medicine.

Nizoral tablets and alcohol

- Drinking alcohol with Nizoral tablets may cause a headache, a rash or make you feel sick
 - You are advised not to drink alcohol whilst taking this medicine
- Talk to your doctor if you are an alcoholic or have been treated for alcoholism. Your doctor will decide if you can have Nizoral tablets.

Pregnancy and breast-feeding

Talk to your doctor before taking Nizoral tablets if you are pregnant, think you may be pregnant or might become pregnant.

You may still be able to take Nizoral tablets if your doctor thinks you need to.

Do not take this medicine if you are breast-feeding. This is because small amounts may pass into the mother's milk.

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

Driving and using machines

Nizoral tablets are not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Nizoral tablets

Nizoral tablets contain lactose. If your doctor has told you that you are intolerant of some sugars, contact them before taking this medicine.

3. How to take Nizoral tablets

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

Taking Nizoral tablets

- Always take Nizoral tablets with food as this helps your body to use the medicine
- Swallow the tablets whole with some liquid
- There must be enough acid in your stomach to make sure that your body can use the medicine. Medicines for indigestion, stomach ulcers or heartburn can affect the stomach producing acid. For this reason you should wait two hours after taking Nizoral tablets before taking any of these other medicines

How much to take

The dose of Nizoral tablets is based on:

- Where the infection is
- What type of fungus is causing it
- Your, or your child's, body weight in kilograms

Your doctor will tell you how many Nizoral tablets to take and for how long.

Adults and children weighing more than 30 kilograms

- The usual dose is one tablet taken once each day
- Your doctor may increase the dose and tell you to take two tablets each day

Children weighing between 15 and 30 kilograms

- One-half tablet taken once each day with a meal

If you take more Nizoral tablets than you should

If you take more Nizoral tablets than you were told to, talk to your doctor or go to the nearest hospital casualty department straight away.

If you forget to take Nizoral tablets

- If you forget to take a dose, take it as soon as you remember. Then keep taking the medicine as your doctor has told you
- Do not take a double dose to make up for the missed dose

When to stop taking Nizoral tablets

Keep taking Nizoral tablets for as long as your doctor has told you.

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 tablets can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Sudden swelling of the face or throat. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction
- Yellowing of the skin or whites of your eyes (jaundice), unusually dark urine, pale stools, abnormal tiredness or fever. These may be signs of liver problems

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

Common (affects less than 1 in 10 people)

- Stomach pain, feeling sick (nausea) or being sick (vomiting)
- Itching (pruritus)

Uncommon (affects less than 1 in 100 people)

- Headache
- Diarrhoea
- Skin rash or reddening
- Sleepiness
- Dizziness

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is classed as unknown:

- lower number of blood platelets that can cause abnormal bleeding
- Insufficiency of the adrenal gland (a small gland close to the kidney) has occurred.
- Increased pressure in the brain (in infants, the fontanelle may bulge),
- Tingling sensation in the hands or feet

- Increased sensitivity to strong sunlight.
- Hair loss
- Heartburn
- Impotence
- Menstrual disorders may be experienced in women, and in men a short-term decrease in testosterone levels can also be experienced and, at higher doses lower sperm count
- Men may get swelling of the breasts.

If you get any of these side effects, or other side effects not listed in this leaflet, tell your doctor or pharmacist straight away.

5. How to store Nizoral tablets

Keep out of the reach and sight of children.

Do not store above 30°C. Store in the original package to protect from moisture.

Do not take Nizoral tablets after the expiry date which is stated on the label. 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 tablets is ketoconazole. Each Nizoral tablet contains 200 mg of ketoconazole.

The other ingredients are maize starch, lactose, polyvidone, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

What Nizoral tablets look like and contents of the pack

Nizoral tablets are white, circular, flat tablets, marked "JANSSEN" on one side and "K/200" on the other. They come in blister packs of 30 tablets.

The product licence is held by:

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

Nizoral tablets are made by:

Janssen-Cilag SpA (Latina), Via C Janssen, 04010 Borgo San Michele, Latina, Italy

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

This leaflet was last approved in June 2010.