

# NIZORAL<sup>®</sup> Tablets

*Ketoconazole*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some of the common questions about NIZORAL tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NIZORAL tablets against the benefits this medicine is expected to have for you.

If you have any concerns about using NIZORAL tablets, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

### What NIZORAL tablets are used for

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NIZORAL tablets are used to treat:

- fungal infections of the skin, hair and mucous membrane that cannot be treated by applying a medicine directly to the infected area
- persistent fungal infections of the vagina
- fungal infections of the mouth, throat and stomach, intestines or other internal organs.

NIZORAL contains ketoconazole which belongs to a group of medicine called antifungals. It works by killing or stopping the growth of certain types of fungi or yeasts that cause the infection.

Your doctor may have prescribed NIZORAL tablets for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

### Before you take NIZORAL tablets

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#### When you must not take it

Do not take NIZORAL tablets if:

- you have an allergy to NIZORAL or any of the ingredients. See **Product Description** at the end of this leaflet for a list of ingredients
- you have liver diseases or are recovering from hepatitis

- you are pregnant.

Do not use NIZORAL tablets with any of the following:

- certain medicines for allergy or hay fever (terfenadine, mizolastine or astemizole)
- cisapride or domperidone(used for certain digestive problems)
- certain medicines used to produce calmness or to help you sleep (midazolam or triazolam)
- certain HMG-Co A reductase inhibitors, such as simvastatin, atorvastatin or lovastatin (used to lower your cholesterol)
- pimozide or sertindole (used to treat mental disorders)
- halofantrine (used to treat malaria)
- levacetylmethadyl (levomethadyl) used for severe pain or to manage addiction
- certain medicines used to treat angina (crushing chest pain) and high blood pressure such as bepridil, epleronone and nisoldipine
- medicines called ergot alkaloids such as ergotamine, dihydroergotamine, ergometrine (ergonovine), methylergometrine (methylergonovine)
- quinidine, disopyramide and dofetilide (used to treat irregular heart beats)
- irinotecan (used to treat cancer)
- everolimus (used to reduce the activity of the body's natural defences).

Do not use NIZORAL tablets if the packaging is torn or shows signs of tampering. Do not use NIZORAL tablets beyond the expiry date (month and year) printed on the pack.

#### Before you start to take it

You **must** tell your doctor if:

- you are pregnant or are planning to become pregnant
- you are breast feeding or wish to breastfeed
- **you know you have a liver problem.** You should not receive NIZORAL tablets if you have acute or chronic liver disease. Liver disorders, sometimes serious, can occur during treatment with NIZORAL tablets. The chances of this happening are greater if you use NIZORAL tablets for long periods of

time, if you know you have liver disorders or if you are allergic to medicines.

Before you start taking NIZORAL tablets, your doctor will have some laboratory tests done to be sure your liver is working properly. As the treatment continues, your doctor will tell you to have a regular blood test because liver disorders can be discovered early in the blood. See also **Side Effects**.

- you have recently taken griseofulvin (an antifungal).

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given NIZORAL tablets.

Your doctor will advise you whether or not to take NIZORAL tablets or if you need to adjust the dose or adapt your treatment.

### **Taking other medicines:**

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

**In particular, NIZORAL tablets must not be taken with some medicines.** Examples are:

- certain medicines for allergy or hayfever (terfenadine, mizolastine or astemizole)
- halofantrine (used to treat malaria)
- levacetylmethadyl (levomethadyl) used for severe pain or to manage addiction
- cisapride or domperidone, (used to treat certain digestive problems)
- certain medicines used to produce calmness or to help you sleep (midazolam or triazolam)
- certain HMG-Co A reductase inhibitors, such as simvastatin, atorvastatin or lovastatin (used to lower your cholesterol)
- pimozide (used to treat mental disorders)
- certain medicines used to treat angina (crushing chest pain) or high blood pressure, such as bepridil, epleronone and nisoldipine
- medicines called ergot alkaloids such as ergotamine, dihydroergotamine, ergometrine (ergonovine), methylergometrine (methylergonovine)
- quinidine, disopyramide and dofetilide (used to treat irregular heart beats)
- irinotecan (used to treat cancer)
- everolimus (used to reduce the activity of the body's natural defences).

**Certain medicines may be affected by NIZORAL tablets or may affect how well NIZORAL tablets work. Your doctor may need to adjust the dose or adapt your treatment. Examples of these medicines are:**

- cyclosporine, tacrolimus and sirolimus (used to help prevent organ transplant rejection or to treat certain problems with the immune system)
- methylprednisolone, budesonide and dexamethasone (medicines given by mouth, injection or inhalation for inflammation within the body, asthma and allergies)
- certain medicines used to treat AIDS, such as indinavir, saquinavir, ritonavir, amprenavir, atazanavir, darunavir and nevirapine
- phenytoin or carbamazepine (used to treat fits)
- busulphan, vinca alkaloids, docetaxel, erlotinib and imatinib (used to treat some cancers)
- medicines taken for diabetes such as repaglinide
- certain drugs for migraine headaches (ergotamine and dihydroergotamine)
- certain calcium channel blockers such as verapamil (used to treat heart or blood vessel problems)
- digoxin (used to treat heart failure)
- anticoagulants (used to slow blood clotting)
- medicines used to regulate fat and body metabolism such as fluticasone
- buspirone and alprazolam (used to treat anxiety)
- alfentanil and fentanyl (used in surgery for pain relief and to help anaesthesia)
- sildenafil (used to treat erectile dysfunction)
- trimetrexate (used to treat certain type of pneumonia)
- tolterodine and solifenacin (used to help control the need to urinate too frequently)
- rifampicin, rifabutin or isoniazid (used to treat tuberculosis)
- medicines which neutralise stomach acid or suppress the production of stomach acid (such as antacids, cimetidine, ranitidine, omeprazole)
- quetiapine (used to treat chemical imbalances in the brain which causes mental illness).

### **Effect of alcohol**

- Some people may feel sick if they drink alcohol during treatment with NIZORAL tablets. You are advised not to drink alcohol when taking NIZORAL tablets.

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## Taking NIZORAL Tablets

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### How much to take

- The usual dose for adults is 1 tablet once daily. Sometimes your doctor may increase this dose to 2 tablets daily.
- The period of treatment may vary between 2 weeks to 6 months. Follow your doctor's directions.

### How to take it

- NIZORAL tablets should be taken during meals or with food. This will make sure that they are fully absorbed by the body.
- Do not take medicines that neutralise stomach acid within 2 hours of taking NIZORAL. This is because sufficient stomach acid is required to ensure that NIZORAL tablet is properly absorbed by the body. If you take medicines that suppress the production of stomach acid, you should take your NIZORAL with an acidic drink, such as a cola beverage.

If you do not understand the instructions provided with this medicines, ask your doctor or pharmacist for help.

### If you forget to take it

- Take the dose you missed as soon as you remember, and then continue to take it as you would normally.
- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Do not take a double dose to make up for the one you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### If you have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- Australia: **13 11 26**
- New Zealand: **0800 POSION or 0800 764 766**

Keep these telephone numbers handy.

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## While you are taking NIZORAL tablets

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### Things you must do

- Always follow your doctor's instructions carefully.
- If you are taking NIZORAL tablets for longer than 2 weeks, you are advised to have a regular blood test (about once a month). This is to detect **liver problems** that may occur during long term treatment with NIZORAL. Liver problems can be recognised by the following symptoms: unusual tiredness, nausea and vomiting, yellowing of the skin or eyes (jaundice), dark urine, pale stools, lack of appetite, abdominal pain and fever. **Stop the treatment immediately and tell your doctor if you notice any of these symptoms.**
- Tell your doctor if you become pregnant while taking NIZORAL tablets.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking NIZORAL tablets.

### Things you must not do

- Do not use NIZORAL to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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## Side Effects

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All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

### Tell your doctor if you experience any of the following:

- indigestion, nausea and vomiting, decreased appetite, increased appetite, abdominal pain, constipation, diarrhoea, excess gas, dry mouth, tongue discolouration, and loss of or abnormal sense of taste may sometimes occur
- a change in menstrual pattern, inability to get or maintain an erection
- headache, dizziness, drowsiness, fatigue, weakness, hot flush, nervousness, inability to sleep, muscle pain, joint pain, sensitivity to light or sunlamps, tingling sensations, decreased number of platelets, swelling of the breast

- unusual hair loss or thinning.

**Tell your doctor immediately if you notice any of the following as you may need urgent medical care:**

- bleeding or bruising more easily than normal
- fever or chills
- numb feeling in your fingers or toes
- swelling of the hands or feet
- skin rash or itching
- dizziness on standing up, especially when getting up from a sitting or lying position
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- blurred vision.

**STOP taking NIZORAL tablets and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:**

- abnormal tiredness, dark urine, pale stools, yellowing of the skin or eyes, nausea, vomiting, lack of appetite, abdominal pain and/or fever
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Men who take NIZORAL tablets for a long time may get swelling of the breasts or a decrease in their level of sperm. These effects will reverse on stopping treatment.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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## After taking NIZORAL tablets

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### Storage

Keep your NIZORAL tablets in the pack until it is time to take them.

Keep NIZORAL tablets in a cool dry place where the temperature is below 25°C.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store NIZORAL tablets, or any other medicine in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

### Disposal

If your doctor tells you to stop taking NIZORAL tablets, or your medicines has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

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## Product Description

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### What it looks like

NIZORAL tablets are white, round, scored tablets. Each tablet is marked "K/200" on one side and "JANSSEN" on the reverse. They are available in foil strips or blisters in cartons of 10 or 30 tablets. The Australian Register Number for the product sold in foil strips is AUST R 13310 and for the product sold in blisters is AUST R 40317.

### Ingredients

Each NIZORAL tablet contains

- 200 milligrams of ketoconazole as the active ingredient
- lactose, povidone, maize starch, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

### Sponsor

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