

MEDICATION GUIDE

NIZORAL[®] (ketoconazole) Tablets

What is the most important information I should know about NIZORAL[®] Tablets?

NIZORAL[®] Tablets is not the only medicine available to treat fungal infections and should only be used when other medicines are not right for you. Talk to your healthcare provider to find out if NIZORAL[®] Tablets are right for you.

NIZORAL[®] Tablets can cause serious side effects, including:

- **liver problems (hepatotoxicity). Some people who were treated with ketoconazole the active ingredient in NIZORAL[®] Tablets, had serious liver problems that led to death or the need for a liver transplant.** Call your healthcare provider right away if you have any of the following symptoms:
 - loss of appetite or start losing weight (anorexia)
 - nausea or vomiting
 - feel tired
 - stomach pain or tenderness
 - dark urine or light colored stools
 - yellowing of your skin or the whites of your eyes
 - fever or rash
- **changes in the electrical activity of your heart called QT prolongation. QT prolongation can cause irregular heart beats that can be life threatening.** This can happen when NIZORAL[®] Tablets are taken with certain medicines, such as dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, and ranolazine. Talk to your healthcare provider about other medicines you are taking before you start taking NIZORAL[®] Tablets. Tell your healthcare provider right away if you feel faint, lightheaded, dizzy, or feel your heart beating irregularly or fast. These may be symptoms related to QT prolongation.

What are NIZORAL[®] Tablets?

- NIZORAL[®] Tablets are prescription medicine used to treat serious fungal infections including: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis.
- NIZORAL[®] Tablets are not for people with fungal nail infections.
- NIZORAL[®] Tablets have not been approved for the treatment of advanced prostate cancer or Cushing's syndrome. The safety and efficacy have not been established.
- NIZORAL[®] Tablets should only be used in children if prescribed by the healthcare provider who has determined that the benefits outweigh the risks.

Who should not take NIZORAL[®] Tablets?

- **Do not take NIZORAL[®] Tablets if you:**
 - have liver problems
 - take simvastatin, or lovastatin. NIZORAL[®] Tablets when taken with these medicines may cause muscle problems.
 - take eplerenone, dihydroergotamine, ergotamine, ergometrine (ergonovine), methylergometrine (methylergonovine) or nisoldipine.
 - take triazolam, midazolam, or alprazolam. Taking NIZORAL[®] Tablets with these medicines may make you very drowsy and make your drowsiness last longer.
 - are allergic to ketoconazole or any of the ingredients in NIZORAL[®] Tablets. See the end of this Medication Guide for a complete list of ingredients in NIZORAL[®] Tablets.

Before you take NIZORAL[®] Tablets, tell your healthcare provider if you:

- have had an abnormal heart rhythm tracing (ECG) or anyone in your family have or have had a heart problem called “congenital long QT syndrome”.
- have adrenal insufficiency.
- are pregnant or plan to become pregnant. It is not known if NIZORAL[®] Tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. NIZORAL[®] Tablets can pass into your breast milk. You and your healthcare provider should decide if you will take NIZORAL[®]

Tablets or breastfeed. You should **NOT** do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using NIZORAL[®] Tablets with certain other medicines may affect each other. Using NIZORAL[®] Tablets with other medicines can cause serious side effects.

How should I take NIZORAL[®] Tablets?

- Take NIZORAL[®] 1 time each day.
- Do not stop taking NIZORAL[®] Tablets without first talking to your healthcare provider.

What should I avoid while taking NIZORAL[®] Tablets?

- Do not drink alcohol while taking NIZORAL[®] Tablets.

What are the possible side effects of NIZORAL[®] Tablets?

NIZORAL[®] Tablets may cause serious side effects, including:

- See **“What is the most important information I should know about NIZORAL[®] Tablets?”**
- **adrenal insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. NIZORAL[®] Tablets may cause adrenal insufficiency if you take a high dose. Your healthcare provider will follow you closely if you have adrenal insufficiency or if you are taking prednisone or other similar medicines for long periods of time. Call your healthcare provider right away if you have symptoms of adrenal insufficiency such as tiredness, weakness, dizziness, nausea, and vomiting.
- **serious allergic reactions.** Some people can have a serious allergic reaction to NIZORAL[®] Tablets. Stop taking NIZORAL[®] Tablets and go to the nearest hospital emergency room right away if you get a rash, itching, hives, fever, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be signs of a serious allergic reaction.
- **muscle problems.** Taking certain medicines with NIZORAL[®] Tablets may cause muscle problems. See **“Who should not take NIZORAL[®] Tablets?”**

The most common side effects of NIZORAL[®] Tablets include nausea, headache,

diarrhea, stomach pain, and abnormal liver function tests.

These are not all the possible side effects of NIZORAL[®] Tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NIZORAL[®] Tablets?

- Store NIZORAL[®] Tablets at room temperature between 59°F to 77°F (15°C to 25°C).
- Keep NIZORAL[®] Tablets dry.

General information about the safe and effective use of NIZORAL[®] Tablets.

Medications are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NIZORAL[®] Tablets for a condition for which it was not prescribed. Do not give NIZORAL[®] Tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about NIZORAL[®] Tablets.

If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about NIZORAL[®] Tablets that is written for health professionals.

What are the ingredients in NIZORAL[®] Tablets?

Active ingredient: ketoconazole.

Inactive ingredients: colloidal silicon dioxide, corn starch, lactose, magnesium stearate, microcrystalline cellulose, and povidone.

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This Medication Guide has been approved by the U.S. Food and Drug Administration