

MEDICATION GUIDE

Ketoconazole

(KEE-toe-KON-a-zole)

Tablets USP, 200 mg

What is the most important information I should know about ketoconazole tablets USP?

Ketoconazole 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 ketoconazole tablets are right for you.

Ketoconazole tablets USP can cause serious side effects, including:

- liver problems (hepatotoxicity). Some people who were treated with ketoconazole the active ingredient in ketoconazole 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 ketoconazole 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 ketoconazole 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 ketoconazole tablets USP?

- Ketoconazole tablets are prescription medicine used to treat serious fungal infections including: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis.
- Ketoconazole tablets are not for people with fungal nail infections.

- Ketoconazole tablets have not been approved for the treatment of advanced prostate cancer or Cushing's syndrome. The safety and efficacy have not been established.
- Ketoconazole 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 ketoconazole tablets USP?

- Do not take ketoconazole tablets if you:
 - have liver problems
 - take simvastatin, and lovastatin. Ketoconazole 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 ketoconazole 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 ketoconazole tablets. See the end of this Medication Guide for a complete list of ingredients in ketoconazole tablets.

Before you take ketoconazole tablets USP, 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 ketoconazole tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Ketoconazole tablets can pass into your breast milk. You and your healthcare provider should decide if you will take ketoconazole 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 ketoconazole tablets with certain other medicines may affect each other. Using ketoconazole tablets with other medicines can cause serious side effects.

How should I take ketoconazole tablets USP?

- Take ketoconazole tablets 1 time each day.
- Do not stop taking ketoconazole tablets without first talking to your healthcare provider.

What should I avoid while taking ketoconazole tablets USP?

- Do not drink alcohol while taking ketoconazole tablets.

What are the possible side effects of ketoconazole tablets USP?

Ketoconazole tablets may cause serious side effects, including:

- See "[WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT KETOCONAZOLE TABLETS USP?](#)"
- **adrenal insufficiency** . Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Ketoconazole 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 ketoconazole tablets. Stop taking ketoconazole 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 ketoconazole tablets may cause muscle problems. See "[WHO SHOULD NOT TAKE KETOCONAZOLE TABLETS USP?](#)"

The most common side effects of ketoconazole tablets include nausea, headache, diarrhea, stomach pain, and abnormal liver function tests.

These are not all the possible side effects of ketoconazole 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.

For more information about Ketoconazole Tablets USP, 200 mg, please contact Burel Pharmaceuticals, Inc. at 1-844-436-7010.

How should I store ketoconazole tablets USP?

- Store at 20°C to 25°C (68° to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
- Keep ketoconazole tablets dry.

General information about the safe and effective use of ketoconazole tablets USP.

Medications are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ketoconazole tablets for a condition for which it was not prescribed. Do not give ketoconazole 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 ketoconazole tablets.

If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about ketoconazole tablets that is written for health professionals.

What are the ingredients in ketoconazole tablets USP, 200 mg?

Active ingredient: ketoconazole.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate and methylcellulose.

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

Manufactured by:

Aavis Pharmaceuticals,
Hoschton, GA 30548

Manufactured for:
Burel Pharmaceuticals, Inc.

Richland, MS 39218

Code. L7020/00
Rev. 02/2020