

PATIENT INFORMATION

Fluconazole (floo-KOE-na-zole) Tablets USP

This leaflet contains important information about fluconazole. It is not meant to take the place of your doctor's instructions. Read this information carefully before you take fluconazole. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about fluconazole.

What Is Fluconazole?

Fluconazole is a tablet you swallow to treat vaginal yeast infections caused by a yeast called *Candida*. Fluconazole helps stop too much yeast from growing in the vagina so the yeast infection goes away.

Fluconazole is different from other treatments for vaginal yeast infections because it is a tablet taken by mouth. Fluconazole is also used for other conditions. However, this leaflet is only about using fluconazole for vaginal yeast infections. For information about using fluconazole for other reasons, ask your doctor or pharmacist. See the section of this leaflet for information about vaginal yeast infections.

What Is a Vaginal Yeast Infection?

It is normal for a certain amount of yeast to be found in the vagina. Sometimes too much yeast starts to grow in the vagina and this can cause a yeast infection. Vaginal yeast infections are common. About three out of every four adult women will have at least one vaginal yeast infection during their life.

Some medicines and medical conditions can increase your chance of getting a yeast infection. If you are pregnant, have diabetes, use birth control pills, or take antibiotics you may get yeast infections more often than other women. Personal hygiene and certain types of clothing may increase your chances of getting a yeast infection. Ask your doctor for tips on what you can do to help prevent vaginal yeast infections.

If you get a vaginal yeast infection, you may have any of the following symptoms:

- itching
- a burning feeling when you urinate
- redness
- soreness
- a thick white vaginal discharge that looks like cottage cheese

What To Tell Your Doctor Before You Start Fluconazole?

Do not take fluconazole if you take certain medicines. They can cause serious problems. Therefore, tell your doctor about all the medicines you take including:

- diabetes medicines such as glyburide, tolbutamide, glipizide
- blood pressure medicines like hydrochlorothiazide, losartan, amlodipine, nifedipine or felodipine
- blood thinners such as warfarin
- cyclosporine, tacrolimus or sirolimus (used to prevent rejection of organ transplants)
- rifampin or rifabutin for tuberculosis
- astemizole for allergies
- phenytoin or carbamazepine to control seizures
- theophylline to control asthma
- cisapride for heartburn
- quinidine (used to correct disturbances in heart rhythm)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- amitriptyline or nortriptyline for depression
- pimozide for psychiatric illness
- amphotericin B or voriconazole for fungal infections
- erythromycin for bacterial infections
- olaparib, cyclophosphamide or vinca alkaloids such as vincristine or vinblastine for treatment of cancer
- fentanyl, alfentanil or methadone for chronic pain
- halofantrine for malaria
- ibrutinib used for treating blood cancer
- lipid lowering drugs such as atorvastatin, simvastatin, and fluvastatin
- non-steroidal anti-inflammatory drugs including celecoxib, ibuprofen, and naproxen
- prednisone, a steroid used to treat skin, gastrointestinal, hematological or respiratory disorders
- antiviral medications used to treat HIV like saquinavir or zidovudine
- tofacitinib for rheumatoid arthritis
- tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline
- vitamin A nutritional supplement

Since there are many brand names for these medicines, check with your doctor or pharmacist if you have any questions.

- are taking any over-the-counter medicines you can buy without a prescription, including natural or herbal remedies.
- have any liver problems.
- have any other medical conditions.
- **are pregnant, plan to become pregnant, or think you might be pregnant. Your doctor will discuss whether fluconazole is right for you. Women who can become pregnant should think about using effective birth control while taking fluconazole.**
- are breast-feeding. Fluconazole can pass through breast milk to the baby.
- are allergic to any other medicines including those used to treat yeast and other fungal infections.
- are allergic to any of the ingredients in fluconazole tablets. The main ingredient of Fluconazole Tablets USP is fluconazole. If you need to know the inactive ingredients, ask your doctor or pharmacist.

Who Should Not Take Fluconazole?

To avoid a possible serious reaction, do NOT take fluconazole if you are taking erythromycin, astemizole, pimozide, quinidine, and cisapride (Propulsid®) since it can cause changes in heartbeat in some people if taken with fluconazole.

How Should I Take Fluconazole?

Take fluconazole by mouth with or without food. You can take fluconazole at any time of the day.

Fluconazole keeps working for several days to treat the infection. Generally the symptoms start to go away after 24 hours. However, it may take several days for your symptoms to go away completely. If there is no change in your symptoms after a few days, call your doctor.

Just swallow 1 fluconazole tablet to treat your vaginal yeast infection.

What Should I Avoid while Taking Fluconazole?

Some medicines can affect how well fluconazole works. Check with your doctor before starting any new medicines within seven days of taking fluconazole.

What Are the Possible Side Effects of Fluconazole?

Like all medicines, fluconazole may cause some side effects that are usually mild to moderate.

The most common side effects of fluconazole are:

- headache
- diarrhea
- nausea or upset stomach
- dizziness
- stomach pain
- changes in the way food tastes

Allergic reactions to fluconazole are rare, but they can be very serious if not treated right away by a doctor. If you cannot reach your doctor, go to the nearest hospital emergency room. Signs of an allergic reaction can include shortness of breath; coughing; wheezing; fever; chills; throbbing of the heart or ears; swelling of the eyelids, face, mouth, neck, or any other part of the body; or skin rash, hives, blisters or skin peeling.

Tell your doctor or pharmacist if you experience skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia), and inflammation of internal organs (liver, lungs, heart, kidneys, and large intestine) as they may be signs of a hypersensitivity reaction (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS)).

Fluconazole has been linked to rare cases of serious liver damage, including deaths, mostly in patients with serious medical problems. Call your doctor if your skin or eyes become yellow, your urine turns a darker color, your stools (bowel movements) are light-colored, or if you vomit or feel like vomiting or if you have severe skin itching.

In patients with serious conditions such as AIDS or cancer, rare cases of severe rashes with skin peeling have been reported. Tell your doctor right away if you get a rash while taking fluconazole.

Fluconazole may cause other less common side effects besides those listed here. If you develop any side effects that concern you, call your doctor. For a list of all side effects, ask your doctor or pharmacist.

Cases of reversible adrenal insufficiency have been reported with fluconazole. Tell your doctor if you experience chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss or abdominal pain.

What to Do for an Overdose

In case of an accidental overdose, call your doctor right away or go to the nearest emergency room.

How to Store Fluconazole

Keep fluconazole and all medicines out of the reach of children.

General Advice about Prescription Medicines

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use fluconazole for a condition for which it was not prescribed. Do not give fluconazole to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about fluconazole. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about fluconazole that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to ANI Pharmaceuticals, Inc. at 1-800-308-6755 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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