

PATIENT INFORMATION

DIFLUCAN® (fluconazole tablets)

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

What Is DIFLUCAN?

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

DIFLUCAN is different from other treatments for vaginal yeast infections because it is a tablet taken by mouth. DIFLUCAN is also used for other conditions. However, this leaflet is only about using DIFLUCAN for vaginal yeast infections. For information about using DIFLUCAN 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 DIFLUCAN?

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

- diabetes medicines you take by mouth such as glyburide, tolbutamide, glipizide
- blood thinners such as warfarin
- cyclosporine (used to prevent rejection of organ transplants)
- rifampin or rifabutin (used for tuberculosis)
- astemizole (used for allergies)
- tacrolimus (used to prevent rejection of organ transplants)
- phenytoin (used for seizures)
- theophylline (used for asthma)
- cisapride (Propulsid[®]; used for stomach acid problems)
- terfenadine (Seldane[®]; used for allergies)

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 DIFLUCAN is right for you.
- are breast-feeding. DIFLUCAN 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 DIFLUCAN. The main ingredient of DIFLUCAN is fluconazole. If you need to know the inactive ingredients, ask your doctor or pharmacist.

Who Should Not Take DIFLUCAN?

To avoid a possible serious reaction, do NOT take DIFLUCAN if you are taking cisapride (Propulsid[®]) since it can cause changes in heartbeat in some people if taken with DIFLUCAN.

How Should I Take DIFLUCAN

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

DIFLUCAN 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.

[caption on the right of the illustration]

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

What Should I Avoid while Taking DIFLUCAN?

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

What Are the Possible Side Effects of DIFLUCAN?

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

The most common side effects of DIFLUCAN are:

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

Allergic reactions to DIFLUCAN 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.

Diflucan 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 DIFLUCAN.

DIFLUCAN 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.

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 DIFLUCAN

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

General Advice about Prescription Medicines

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

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

You can also visit the DIFLUCAN Internet site at www.diflucan.com.



Distributed by

Roerig

Division of Pfizer Inc, NY, NY 10017

LAB-0380-2.0

Revised April 2008