

<p><b>PATIENT INFORMATION</b>  <b>Fluconazole (floo-KOE-na-zole) Tablets USP</b></p> <p>This leaflet contains important information about fluconazole. It is not meant to take the place of your healthcare provider's instructions. Read this information carefully before you take fluconazole. Ask your healthcare provider if you do not understand any of this information or if you want to know more about fluconazole.</p>
<p><b>What is Fluconazole?</b>  Fluconazole is a prescription medicine used 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.</p> <p>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 healthcare provider. See the section of this leaflet for information about vaginal yeast infections.</p>
<p><b>What is a vaginal yeast infection?</b>  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.</p> <p>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 healthcare provider for tips on what you can do to help prevent vaginal yeast infections.</p> <p>If you get a vaginal yeast infection, you may have any of the following symptoms:</p> <ul style="list-style-type: none"> <li>• itching</li> <li>• a burning feeling when you urinate</li> <li>• redness</li> <li>• soreness</li> <li>• a thick white vaginal discharge that looks like cottage cheese</li> </ul>
<p><b>Do not take Fluconazole if you</b></p> <ul style="list-style-type: none"> <li>• take the following medicines: <ul style="list-style-type: none"> <li>○ quinidine</li> <li>○ erythromycin</li> <li>○ pimozone</li> </ul> </li> <li>• are allergic to fluconazole, the active ingredient in fluconazole tablets, or any of the ingredients in fluconazole tablets. See the end of this Patient Information leaflet for a complete list of ingredients in fluconazole tablets.</li> </ul>
<p><b>Before you take Fluconazole, tell your healthcare provider about all of your medical conditions, if you:</b></p> <ul style="list-style-type: none"> <li>• have liver problems</li> <li>• have kidney problems</li> <li>• have heart problems including heart arrhythmias</li> <li>• have hypokalemia (low potassium)</li> <li>• are pregnant or plan to become pregnant. Tell your healthcare provider right away if you become pregnant while taking fluconazole. You and your healthcare provider will decide if fluconazole is right for you. If you may become pregnant you should use a birth-control (contraceptive) method while taking fluconazole and for 1 week after your final dose.</li> <li>• are breastfeeding or plan to breastfeed. Fluconazole can pass into your breastmilk. Talk to your healthcare provider about the best way to feed your baby while you are taking fluconazole.</li> </ul> <p><b>Before you start taking Fluconazole, tell your healthcare provider about all the medicines you take,</b> including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take:</p> <ul style="list-style-type: none"> <li>• diabetes medicines such as glyburide, tolbutamide, glipizide</li> <li>• blood pressure medicines like hydrochlorothiazide, losartan, amlodipine, verapamil, nifedipine or felodipine</li> <li>• blood thinners such as warfarin</li> <li>• cyclosporine, tacrolimus or sirolimus (used to prevent rejection of organ transplants)</li> <li>• rifampin or rifabutin for tuberculosis</li> <li>• phenytoin or carbamazepine to control seizures</li> <li>• theophylline to control asthma</li> <li>• quinidine (used to correct disturbances in heart rhythm)</li> <li>• amiodarone (used for treating uneven heartbeats 'arrhythmias')</li> <li>• amitriptyline or nortriptyline for depression</li> <li>• pimozone for psychiatric illness</li> <li>• amphotericin B or voriconazole for fungal infections</li> <li>• erythromycin for bacterial infections</li> <li>• olaparib, cyclophosphamide or vinca alkaloids such as vincristine or vinblastine for treatment of cancer</li> <li>• fentanyl, alfentanil or methadone for chronic pain</li> <li>• ibrutinib used for treating blood cancer</li> <li>• lemborexant, used for the treatment of insomnia</li> <li>• lipid lowering drugs such as atorvastatin, simvastatin, and fluvastatin</li> <li>• non-steroidal anti-inflammatory drugs including celecoxib, ibuprofen, and naproxen</li> <li>• prednisone, a steroid used to treat skin, gastrointestinal, hematological or respiratory disorders</li> <li>• antiviral medications used to treat HIV like saquinavir or zidovudine</li> <li>• tofacitinib for rheumatoid arthritis</li> <li>• vitamin A nutritional supplement</li> <li>• tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline</li> </ul> <p>Since there are many brand names for these medicines, check with your healthcare provider or pharmacist if you have any questions.</p>

<p><b>How should I take Fluconazole?</b></p> <ul style="list-style-type: none"> <li>• Take fluconazole exactly as your healthcare provider tells you to.</li> <li>• Take fluconazole by mouth with or without food.</li> <li>• If you take too much fluconazole, call your healthcare provider or go to the nearest emergency room right away.</li> </ul>
<p><b>What should I avoid while taking Fluconazole?</b>  Fluconazole can cause dizziness and seizures. Do not drive or operate machinery until you know how fluconazole affects you.</p>
<p><b>What are the possible side effects of Fluconazole?</b>  <b>Fluconazole may cause serious side effects including:</b></p> <ul style="list-style-type: none"> <li>• <b>serious liver problems.</b> Some people with serious medical problems have developed serious liver problems that became life-threatening or caused death while taking fluconazole. Sometimes these liver problems can be reversed when you stop taking fluconazole. Tell your healthcare provider right away if you have symptoms of serious liver problems including: <ul style="list-style-type: none"> <li>○ dark colored urine</li> <li>○ light-colored stools</li> <li>○ severe skin itching</li> <li>○ tiredness</li> <li>○ yellowing of the skin and eyes (jaundice)</li> <li>○ vomiting</li> <li>○ loss of appetite</li> </ul> </li> <li>• <b>serious allergic reactions:</b> In rare cases, serious allergic reactions (anaphylaxis) have happened while taking fluconazole. Stop taking fluconazole, call your healthcare provider or go to the nearest hospital emergency room right away if you get any signs or symptoms of an allergic reaction including: <ul style="list-style-type: none"> <li>○ shortness of breath</li> <li>○ coughing</li> <li>○ fever</li> <li>○ skin rash, hives, blisters or skin peeling</li> <li>○ swelling of the eyelids, face, mouth, neck, or any other part of the body</li> <li>○ wheezing</li> <li>○ throbbing of the heart or ears</li> <li>○ chills</li> </ul> </li> <li>• <b>serious skin problems.</b> Some people with serious medical problems have developed serious skin problems that have caused death while taking fluconazole. Tell your healthcare provider right away if you develop a rash while taking fluconazole.</li> </ul> <p><b>The most common side effects of fluconazole include:</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• dizziness</li> <li>• diarrhea</li> <li>• stomach pain</li> <li>• nausea or upset stomach</li> <li>• changes in the way food tastes</li> </ul> <p><b>Other side effects include:</b></p> <ul style="list-style-type: none"> <li>• <b>adrenal insufficiency:</b> Some people who have taken fluconazole developed adrenal insufficiency that was reversible. Tell your healthcare provider right away if you have symptoms of adrenal insufficiency including: <ul style="list-style-type: none"> <li>○ long lasting fatigue</li> <li>○ stomach pain</li> <li>○ weight loss</li> <li>○ vomiting</li> <li>○ nausea</li> <li>○ loss of appetite</li> <li>○ muscle weakness</li> <li>○ dizziness</li> </ul> </li> <li>• <b>dizziness or seizures.</b></li> </ul> <p>These are not all the possible side effects of fluconazole. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>
<p><b>How should I store Fluconazole?</b>  Store fluconazole tablets below 86°F (30°C).  <b>Keep fluconazole tablets and all medicines out of the reach of children.</b></p>
<p><b>General information about the safe and effective use of Fluconazole.</b>  Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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.  You can ask your healthcare provider for information about fluconazole that is written for health professionals.</p>
<p><b>What are the ingredients in Fluconazole?</b>  <b>Active ingredient:</b> fluconazole  <b>Inactive ingredients:</b> croscarmellose sodium, dibasic calcium phosphate anhydrous, FD&amp;C Red No. 40 aluminum lake, magnesium stearate, microcrystalline cellulose and povidone.</p> <p>Manufactured by:  ANI Pharmaceuticals Canada, Inc.  Oakville, ON L6H 1M5, Canada</p> <p>Distributed by:  ANI Pharmaceuticals, Inc.  Baudette, MN 56623</p> 

This Patient Information has been approved by the U.S. Food and Drug Administration  
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