

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr MYLAN-FLUCONAZOLE

Fluconazole Tablets

Read this carefully before you start taking MYLAN-FLUCONAZOLE and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MYLAN-FLUCONAZOLE.

What is MYLAN-FLUCONAZOLE used for?

MYLAN-FLUCONAZOLE is used to treat fungal infections. These are infections caused by fungi, including yeasts. MYLAN-FLUCONAZOLE can also be used to stop you from getting a fungal infection.

How does MYLAN-FLUCONAZOLE work?

MYLAN-FLUCONAZOLE belongs to a group of medicines called antifungals. It helps to stop fungal growth.

What are the ingredients in MYLAN-FLUCONAZOLE?

Medicinal ingredients: Fluconazole

Non-medicinal ingredients: microcrystalline cellulose, dibasic calcium phosphate anhydrous, povidone, croscarmellose sodium, FD & C Red No. 40, aluminum lake dye, and magnesium stearate.

MYLAN-FLUCONAZOLE comes in the following dosage forms:

tablets: 50 mg and 100 mg

Do not use MYLAN-FLUCONAZOLE if:

- you have ever had an allergic reaction to fluconazole or any of the other ingredients of MYLAN-FLUCONAZOLE (see What are the ingredients in MYLAN-FLUCONAZOLE?)
- you have ever had an allergic reaction to other medicines you have taken to treat a fungal infection.
- you are taking any of the following:
 - Erythromycin (an antibiotic for treating infections)
 - Pimozide (for treating schizophrenia)
 - Quinidine (used for irregular heartbeats)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYLAN-FLUCONAZOLE. Talk about any health conditions or problems you may have, including if you:

- have liver or kidney problems
- have abnormal levels of potassium, calcium or magnesium in your blood

- have heart problems including problems with your heart rhythm such as QT prolongation

Other warnings you should know about:

Pregnancy and Breastfeeding:

- Do not get pregnant while you are taking MYLAN-FLUCONAZOLE. If you are pregnant, think you might be pregnant or are thinking of becoming pregnant talk to your healthcare professional.
- MYLAN-FLUCONAZOLE can harm your unborn baby. It can also cause you to have a miscarriage.
- MYLAN-FLUCONAZOLE must only be used in pregnancy to treat life-threatening fungal infections.
- If you are able to get pregnant you must use effective birth control while you are taking MYLAN-FLUCONAZOLE and for 1 week after you stop taking MYLAN-FLUCONAZOLE. Talk to your healthcare professional about the birth control options that are right for you.
- You should not breastfeed while you are taking MYLAN-FLUCONAZOLE. MYLAN-FLUCONAZOLE passes into breastmilk. Talk to your healthcare professional if you are breastfeeding or planning to breastfeed.

Serious skin problems: Serious skin problems, including **Stevens-Johnson syndrome** and **Drug reaction with eosinophilia and systemic symptoms (DRESS)**, have occurred in people taking fluconazole. These skin conditions are more likely to happen if you have AIDS or cancer. In rare cases they have been fatal. If you get a rash while taking MYLAN-FLUCONAZOLE tell your healthcare professional immediately. See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

Driving and using machines: MYLAN-FLUCONAZOLE can cause dizziness and seizures. Do not drive or operate machinery until you know how MYLAN-FLUCONAZOLE affects you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MYLAN-FLUCONAZOLE:

- Abrocitinib (used to treat a skin condition called “atopic dermatitis.” This is a type of eczema).
- Alfentanil, fentanyl or methadone (used to treat pain)
- Amiodarone (used for irregular heartbeats)
- Amitriptyline, nortriptyline (used to treat migraine and other conditions)
- Amphotericin B and Voriconazole (used to treat fungal infections)
- Benzodiazepines such as midazolam, triazolam, or similar medicines (used to help you sleep or for anxiety)
- Calcium channel blockers or losartan (for lowering blood pressure)
- Carbamazepine or phenytoin (used to control epilepsy)
- Celecoxib (used to treat some types of arthritis and certain other types of pain)
- Cimetidine (for heartburn and peptic ulcers)
- Coumarin-Type or Indanedione Anticoagulants (used to thin the blood to prevent blood clots)
- Cyclophosphamide, or vinca alkaloids (for treating some forms of cancer)
- Cyclosporine, sirolimus or tacrolimus (to prevent transplant rejection)

- Halofantrine (to treat malaria)
- HMG-CoA reductase inhibitors (statins) (for lowering cholesterol)
- Ibrutinib (for treating some forms of cancer)
- Ivacaftor (for treating cystic fibrosis)
- Lemborexant (for treating insomnia)
- Lurasidone (for treating brain disorder)
- Medicines for treating infections (antibiotics) such as azithromycin, erythromycin, rifampin or rifabutin
- Non-steroidal anti-inflammatory drugs (such as acetylsalicylic acid and ibuprofen) that are used to treat pain and fever
- Olaparib (for treating some forms of cancer)
- Oral Contraceptives
- Prednisone (used to treat many types of inflammatory and allergic conditions)
- Saquinavir or zidovudine, also known as AZT (used in HIV-infected patients)
- Sulfonylureas and other Oral Hypoglycemics (medicines for diabetes)
- Theophylline (used to control asthma)
- Tofacitinib (used to treat rheumatoid arthritis)
- Tolvaptan (used to treat some type of kidney disease)
- Vitamin A (as a trans-retinoid acid used to treat acne)
- Water tablets (diuretics), such as hydrochlorothiazide, (used to treat fluid retention and high blood pressure)

How to take MYLAN-FLUCONAZOLE:

- Take MYLAN-FLUCONAZOLE as directed by your healthcare professional.

Usual dose:

Adults: 100 to 200 mg daily.

Your healthcare professional will decide on your dose and how long you should take MYLAN-FLUCONAZOLE based on the type of infection being treated.

Children: Your healthcare professional will decide on the dose and how long your child should take MYLAN-FLUCONAZOLE based on your child’s weight and the type of infection being treated.

Overdose:

If you think you, or a person you are caring for, have taken too much MYLAN-FLUCONAZOLE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double dose.

What are possible side effects from using MYLAN-FLUCONAZOLE?

These are not all the possible side effects you may have when taking MYLAN-FLUCONAZOLE. If you experience any side effects not listed here, tell your healthcare professional.

- Headache.
- Skin rash.
- Abdominal pain.
- Diarrhea.
- Nausea and vomiting.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Skin problems (Stevens-Johnson syndrome): rash, blisters, itching all over the body, reddening of the skin or itchy red spots, swelling of eyelids, face or lips, peeling or lost skin			✓
- Drug reaction with eosinophilia and systemic symptoms (DRESS): severe rash, fever, swollen lymph glands		✓	
Liver problems: abdominal pain, dark urine, fever, light-colored stool, yellowing of the skin and eyes			✓
COMMON			
Heart problems (QT prolongation, torsade de pointes): unstable or irregular heartbeat, chest pain, shortness of breath, dizziness, fainting			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reaction: swelling of the face, throat, mouth, extremities, difficulty in breathing, rash or itching			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store MYLAN-FLUCONAZOLE between 15°C to 30°C.

Keep out of reach and sight of children.

If you want more information about MYLAN-FLUCONAZOLE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.mylan.ca, or by calling 1-844-596-9526.

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