

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDIFLUCAN®

fluconazole tablets

fluconazole powder for oral suspension

fluconazole injection

Read this carefully before you start taking DIFLUCAN 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 DIFLUCAN.

What is DIFLUCAN used for?

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

How does DIFLUCAN work?

DIFLUCAN belongs to a group of medicines called antifungals. It helps to stop fungal growth.

What are the ingredients in DIFLUCAN?

Medicinal ingredients: Fluconazole

Non-medicinal ingredients:

DIFLUCAN tablets[§]: croscarmellose sodium, dibasic calcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose, povidone, FD&C Red #40 aluminum lake dye

DIFLUCAN powder for oral suspension: citric acid, colloidal silicon dioxide, natural orange flavour, sodium benzoate, sodium citrate, sucrose, titanium dioxide, xanthan gum.

DIFLUCAN injection: sodium chloride solution 9 mg/mL

DIFLUCAN comes in the following dosage forms:

tablets[§]: 50 mg and 100 mg

powder for oral suspension: 50 mg / 5 mL (when reconstituted)

injection: sterile aqueous solution; 2 mg / mL

[§]Currently not commercially available in Canada

Do not use DIFLUCAN if:

- you have ever had an allergic reaction to fluconazole or any of the other ingredients of DIFLUCAN (see What are the ingredients in DIFLUCAN?)

- 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 DIFLUCAN. 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
- have hereditary fructose, glucose/galactose malabsorption or sucrase-isomaltase deficiency as DIFLUCAN powder for oral suspension contains sucrose.

Other warnings you should know about:

Pregnancy and Breastfeeding:

- Do not get pregnant while you are taking DIFLUCAN. If you are pregnant, think you might be pregnant or are thinking of becoming pregnant talk to your healthcare professional.
- DIFLUCAN can harm your unborn baby. It can also cause you to have a miscarriage.
- DIFLUCAN 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 DIFLUCAN and for 1 week after you stop taking DIFLUCAN. Talk to your healthcare professional about the birth control options that are right for you.
- You should not breastfeed while you are taking DIFLUCAN. DIFLUCAN 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 DIFLUCAN. 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 DIFLUCAN 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: DIFLUCAN can cause dizziness and seizures. Do not drive or operate machinery until you know how DIFLUCAN 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 DIFLUCAN:

- 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 DIFLUCAN:

- Take DIFLUCAN as directed by your healthcare professional.
- DIFLUCAN injection will be given to you directly into a vein by a healthcare professional.
- DIFLUCAN powder for oral suspension will be prepared by your pharmacist. Shake the bottle well before each use.

Usual dose:

Adults: 100 to 200 mg daily.

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

Children: Your healthcare professional will decide on the dose and how long your child should take DIFLUCAN 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 DIFLUCAN, 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 DIFLUCAN?

These are not all the possible side effects you may have when taking DIFLUCAN. 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.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:

DIFLUCAN tablets: Store at room temperature (15 to 30°C).

DIFLUCAN powder for oral suspension: The suspension prepared by your pharmacist can be stored between 5 to 30 °C for 14 days. Do not freeze. Discard unused portion after 14 days.

DIFLUCAN injection: Store at room temperature (15 to 30°C). Do not freeze.

Keep out of reach and sight of children.

If you want more information about DIFLUCAN:

- 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.pfizer.ca, or by calling 1-800-463-6001 (Medical Information).

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