

CONSUMER INFORMATION

PrDIFLUCAN®
(Fluconazole)

**Powder for Oral Suspension
(50 mg / 5 mL) (when reconstituted)**

Sterile aqueous solution for infusion (2 mg / mL)

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DIFLUCAN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

DIFLUCAN is one of a group of medicines called antifungals.

DIFLUCAN is prescribed by your doctor and is used to treat infections caused by fungi including yeasts and may also be used to stop you from getting a fungal infection. The most common cause of fungal infection is a yeast called *Candida*.

What it does:

DIFLUCAN selectively interferes with the normal sterol production in fungi and helps to stop fungal growth.

When it should not be used:

Do not take DIFLUCAN if you have ever had an allergic reaction to:

- any of the ingredients of DIFLUCAN (see What the nonmedicinal ingredients are)
- other medicines you have taken to treat a fungal infection.

The symptoms may include itching, reddening of the skin or difficulty in breathing.

Do not take DIFLUCAN if you are taking any of the following drugs:

- Erythromycin (an antibiotic for treating infections),
- Pimozide (for treating schizophrenia) and
- Quinidine (used for irregular heartbeats).

What the medicinal ingredient is:

Fluconazole

What the important non-medicinal ingredients are:

DIFLUCAN Powder for Oral Suspension contains the following non-medicinal ingredients: sucrose, sodium citrate, citric acid, sodium benzoate, titanium dioxide, colloidal silicon dioxide, xanthan gum and natural orange flavour.

DIFLUCAN aqueous solution for infusion contains the following non-medicinal ingredient: sodium chloride solution 9 mg/mL

What dosage forms it comes in:

DIFLUCAN Tablets[§] (50 mg and 100 mg)
DIFLUCAN Powder for Oral Suspension (50 mg / 5 mL) (when reconstituted)
DIFLUCAN Sterile aqueous solution for infusion (2 mg / mL)

[§] Not commercially available in Canada

WARNINGS AND PRECAUTIONS

BEFORE you use DIFLUCAN talk to your doctor or pharmacist if you:

- **have liver or kidney problems**
- **are allergic to any other medicines including those used to treat yeast and other fungal infections**
- **have abnormal levels of potassium, calcium or magnesium in your blood**
- are breast-feeding or planning to breast-feed. DIFLUCAN is excreted in human breast milk. Breast-feeding is not recommended.
- have heart disease such as heart conditions, blood disorders or any other medical conditions.
- are driving and using machines. It should be taken into account that occasionally dizziness or seizures may occur.
- are taking or have taken any other medicines, including medicines obtained without a prescription
- have hereditary fructose, glucose/galactose malabsorption and sucrase-isomaltase deficiency as DIFLUCAN powder for oral suspension contains sucrose.
- Have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption because DIFLUCAN capsules contain lactose.
- **Use in Children**
Your doctor will decide whether this medication is suitable for your child.
- **Use in Pregnancy**
 - DIFLUCAN may cause permanent harm to your unborn baby and may cause a miscarriage

of your pregnancy.

- If you are pregnant or planning to become pregnant, talk to your doctor.
- DIFLUCAN should not be used in pregnancy except in severe or life-threatening infection.
- Your doctor will decide if DIFLUCAN should be used in your situation.

If you are a woman of child-bearing potential then:

- Avoid becoming pregnant during treatment
- Use effective contraception during treatment and for 1 week after treatment
- Tell your doctor if you become pregnant during treatment.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with DIFLUCAN include:

- 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)
- 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)

[§] Indanedione Anticoagulants not commercially available in Canada

PROPER USE OF THIS MEDICATION

Usual dose:

Take DIFLUCAN only as directed by your doctor.

Overdose:

In case of drug overdose, contact a health care practitioner, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, DIFLUCAN may cause some side effects.

The most common side effects are:

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Exfoliative skin disorders: Severe skin reactions, such as a rash that causes blistering, itching all over the body, reddening of the skin or itchy red spots, swelling of eyelids, face or lips, peeling or lost skin			√
Hepatic necrosis (death of liver cells which may cause abdominal pain and dark urine, fever, light-colored stool, and jaundice (a yellow appearance to the skin and white portion of the eyes))			√
Heart conditions: Unstable or irregular heartbeat (e.g. QT prolongation, torsade de pointes)			√
Allergic Reaction with symptom such as swelling of the face, throat, mouth, extremities, difficulty in breathing, rash or itching			√

This is not a complete list of side effects. For any unexpected effects while taking DIFLUCAN, contact your doctor or pharmacist immediately.

HOW TO STORE IT

Store at room temperature (15-30°C). Do not freeze. Keep out of reach and sight of children. The reconstituted suspension is stable for 2 weeks at 5-30°C

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at: www.pfizer.ca or by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001 (Medical Information).

This leaflet was prepared by Pfizer Canada ULC
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