

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### DIFLUCAN® ONE

#### (Fluconazole Capsule)

Read this carefully before you start taking **DIFLUCAN ONE** 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 ONE**.

#### What is **DIFLUCAN ONE** used for?

**DIFLUCAN ONE** is indicated for the treatment of vaginal yeast (fungal) infections. It can be taken anytime, anywhere to relieve itching, burning and discharge associated with vaginal yeast infections. **DIFLUCAN ONE** is a clinically proven, effective single-dose cure for most vaginal yeast infections that starts to work in 1 day.

#### *What is a Yeast Infection?*

A "yeast infection" may occur any time there is an overgrowth of yeast organisms in the vagina. The vagina normally has bacteria and yeast organisms present. Under some conditions, the number of yeast organisms rises, irritating the tissues of the vagina and vaginal opening.

Conditions that make this more likely to occur:

- illness
- use of antibiotics
- changes in hormone levels
- pregnancy
- use of oral contraceptive pills
- just before a woman's period
- diabetes
- hot humid weather
- continuous use of panty liners
- tight, non-breathing clothing
- nylon underwear, pantyhose, wet bathing suits or damp workout wear
- perfumed soaps, bubble baths or douching may cause vaginal irritation and upset the normal balance

Refrain from vaginal intercourse when you have a yeast infection to avoid infecting your partner and to minimize additional discomfort. If your partner has any genital itching, redness or discomfort, they should talk to their doctor and mention that you are treating a yeast infection.

*When a "yeast infection" occurs, the body responds with:*

- an increase in vaginal secretions
- secretions are generally thick and sticky (cheesy or curd-like, similar to cottage cheese), but odourless
- secretions that are irritating to the tissues of the vaginal area
- itching, redness, and swelling of the vaginal area
- red spots or sores may develop, especially if the area has been scratched
- soreness in the vagina
- pain during sexual relations is common.

### **How does DIFLUCAN ONE work?**

**DIFLUCAN ONE** is an antifungal medication. The active ingredient fluconazole works by stopping the growth of the fungi that cause vaginal yeast infections.

### **What are the ingredients in DIFLUCAN ONE?**

Medicinal ingredient: Fluconazole

Non-medicinal ingredients: Colloidal silicon dioxide, gelatin, Lactose, magnesium stearate, maize starch, sodium lauryl sulphate, titanium dioxide

### **DIFLUCAN ONE comes in the following dosage forms:**

Capsule, 150 mg

### **Do not use DIFLUCAN ONE if:**

- you are allergic to fluconazole, related azoles (e.g. clotrimazole / miconazole) or other ingredients in the product (see **What are the ingredients in DIFLUCAN ONE?**)
- you are taking allergy drugs (e.g. astemizole\* / terfenadine\*)
- you are taking cisapride\*, quinidine, erythromycin, pimozone or amiodarone

\*not marketed in Canada

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

- you are having your first yeast infection
- you have frequent vaginal infections
- you are at increased risk for sexually transmitted diseases, have multiple sexual partners or change partners often
- you have heart disease
- using in children less than 12 years old

### **Other warnings you should know about:**

Yeast infections do not cause:

- Fever

- Chills
- Abdominal pain
- Nausea
- Vomiting
- Diarrhea
- Pain upon urination
- Unexplained pain in your lower back or either shoulder
- Foul-smelling discharge

Consult your doctor immediately if you have these symptoms, as they could be signs of a more serious condition.

**Pregnancy and Breastfeeding:**

- You should not use **DIFLUCAN ONE** if you are pregnant or trying to become pregnant.
- You should not use **DIFLUCAN ONE** if you are breastfeeding.

There have been reports of spontaneous abortion of the foetus or birth defects. If you could become pregnant while taking this medicine, you should consider using a reliable means of contraception for approximately 1 week after the dose. If you become pregnant while taking this medicine, contact your doctor.

**Driving and using machines:** **DIFLUCAN ONE** can cause dizziness and seizures. Do not drive or operate machinery until you know how **DIFLUCAN ONE** 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 ONE:**

- Abrocitinib (used to treat atopic dermatitis (a type of eczema)).
- Antibiotics (rifabutin or rifampin)
- Astemizole\* or terfenadine\* (used to treat allergies)
- Blood thinners (warfarin or similar drugs)
- Cimetidine or cisapride\* (for control of heartburn)
- Cyclosporine or tacrolimus (used to prevent organ transplant rejection)
- Glyburide, glipizide or tolbutamide (medicines for diabetes)
- Ibrutinib (used to treat cancer)
- Ivacaftor (used to treat cystic fibrosis)
- Lemborexant (used to treat insomnia)
- Lurasidone (used to treat brain disorder)
- Midazolam or triazolam (used to help you sleep or for anxiety)
- Oral Contraceptives
- Phenytoin (used to control epilepsy)

- Prednisone (steroid used to treat skin, stomach, blood or breathing disorders)
- Statins (cholesterol lowering agents)
- Theophylline (used to control asthma)
- Tolvaptan (used to treat low blood sodium)
- Water pills (diuretics), such as hydrochlorothiazide
- Zidovudine (used to treat AIDS/HIV)

\* not marketed in Canada

### How to take DIFLUCAN ONE:

Consult your doctor if this is your first yeast infection, or if you have a second yeast infection in less than 2 months after treating a prior infection.

### Usual dose:

Adults (≥12 years old): Take **DIFLUCAN ONE** by mouth as a one-time only dose, with or without food, or as directed by your doctor. DO NOT take more than one dose for this infection. If your symptoms have not improved within 3 days and disappeared in 7 days, contact your doctor.

Clearing a yeast infection does take time. Although **DIFLUCAN ONE** is taken only once, **DIFLUCAN ONE** therapy does not cure the infection in just one day, the medication remains active in your body for several days. Most patients can expect to see symptom relief begin within 24 hours after taking the capsule. As **DIFLUCAN ONE** works to cure the infection, symptoms will lessen and eventually disappear.

### Overdose:

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

### What are possible side effects from using DIFLUCAN ONE?

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

Like all medicines, **DIFLUCAN ONE** may cause some side effects.

The most common side effects are:

- Headache,
- Abdominal pain,
- Diarrhea,
- Nausea,
- Vomiting.

Most reported side effects were mild to moderate in nature.

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	
<b>VERY COMMON</b>			
<b>Skin disorders:</b> skin eruptions, new rash or irritations or allergy symptoms such as hives			√
<b>Liver problems:</b> abdominal pain, dark urine, fever, light-colored stool, yellowing of the skin and eyes			√
<b>COMMON</b>			
<b>Heart problems:</b> unstable or irregular heartbeat, chest pain, shortness of breath, dizziness, fainting			√
<b>RARE</b>			
<b>Severe allergic reactions</b> (swelling of face, eyes, mouth, hands and feet)			√

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:**

Store at room temperature (15-30°C). Do not freeze.

Keep out of reach and sight of children.

**If you want more information about DIFLUCAN ONE:**

- 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](http://www.pfizer.ca), or by calling 1-800-463-6001 (Medical Information).

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