

PART III: CONSUMER INFORMATION**DIFLUCAN ONE***

Fluconazole Capsule 150mg

This leaflet is part III of a three-part "Product Monograph" published when DIFLUCAN ONE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DIFLUCAN ONE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is 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.

What it does:

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

When it should not be used:

Do not use if you are:

- pregnant
- trying to become pregnant
- nursing
- allergic to fluconazole, related azoles (e.g. clotrimazole / miconazole) or other ingredients in the product
- taking allergy drugs (e.g. astemizole* / terfenadine*)
- taking cisapride*

*not marketed in Canada

What the medicinal ingredient is:

Fluconazole 150mg (Oral Capsule)

What the important nonmedicinal ingredients are:

Lactose, maize starch, colloidal silicon dioxide, magnesium stearate and sodium lauryl sulphate; the capsule shell contains gelatin and titanium dioxide.

What dosage forms it comes in:

DIFLUCAN ONE Capsules are available as hard white gelatin capsules, marked with Pfizer logo. Each capsule contains 150 mg of fluconazole. Supplied as a unit dose blister polyvinyl chloride (PVC) pack of 1 capsule. Each capsule contains 150 mg of fluconazole.

WARNINGS AND PRECAUTIONS

BEFORE USING DIFLUCAN ONE talk to your doctor or pharmacist 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

There have been reports of spontaneous abortion of the fetus 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.

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.

INTERACTIONS WITH THIS MEDICATION

BEFORE you use **DIFLUCAN ONE** talk to your doctor or pharmacist if you are taking any other drug especially drugs for:

- AIDS/HIV (zidovudine)
- Allergies (Astemizole*, Terfenadine*)
- Asthma (theophylline)
- Antibiotics (rifabutin, rifampicin)
- Blood Thinners (warfarin or similar drugs)
- Diabetes (glyburide, glipizide, tolbutamide)
- Diuretics (hydrochlorothiazide)
- Epilepsy (phenytoin)

- Immune System suppression (cyclosporine, tacrolimus)
- Stomach (cimetidine, cisapride*)
- Sedation (midazolam, triazolam)
- Steroid used to treat skin, stomach, blood or breathing disorders (prednisone)

* not marketed in Canada

PROPER USE OF THIS MEDICATION

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:

In case of accidental overdose call a doctor or poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects in clinical studies were headache, nausea, abdominal pain, and diarrhea. Most reported side effects were mild to moderate in nature.

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

Stop use and contact a doctor or pharmacist if you: develop skin eruptions, experience new rash or irritations or allergy symptoms such as hives. Rarely, severe allergic reactions (swelling of face, eyes, mouth, hands and feet) have occurred.

HOW TO STORE IT

Store between 15°-30°C.
Keep out of reach of children.

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Pfizer Consumer Healthcare, a division of Pfizer Canada Inc., Mississauga, Ontario L5R 4B2, at: 1-888-869-9384

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