

PART III: CONSUMER INFORMATION

Pr pms-FLUCONAZOLE

Fluconazole Tablets, House Standard

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

ABOUT THIS MEDICATION

What the medication is used for:

pms-FLUCONAZOLE is one of a group of medicines called antifungals.

pms-FLUCONAZOLE 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:

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

When it should not be used:

Do not take pms-FLUCONAZOLE if you have ever had an allergic reaction to:

- any of the ingredients of pms-FLUCONAZOLE (see What the non-medicinal 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 pms-FLUCONAZOLE 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 non-medicinal ingredients are:

Croscarmellose Sodium, Dibasic Calcium Phosphate Anhydrous, FD&C Red No. 3 and No. 40 Lake Dye, Magnesium Stearate, Microcrystalline Cellulose and Povidone.

What dosage forms it comes in:

Tablets: 50 mg & 100 mg

WARNINGS AND PRECAUTIONS

BEFORE you use pms-FLUCONAZOLE 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. Fluconazole 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

Use in Children

Your doctor will decide whether this medication is suitable for your child.

Use in Pregnancy

- Fluconazole 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.
- Fluconazole should not be used in pregnancy except in severe or life-threatening infection.
- Your doctor will decide if fluconazole 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 pms-FLUCONAZOLE 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)
- 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)
- 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 pms-FLUCONAZOLE 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, pms-FLUCONAZOLE 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-coloured 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, <i>torsades de pointes</i>)			√
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 pms-FLUCONAZOLE, contact your doctor or pharmacist immediately.

HOW TO STORE IT

Store between 15°C and 30°C.

Keep out of reach and sight of children.

Reporting Side Effects

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

- Visiting the Web page on Adverse Reaction Reporting (<http://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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, Pharmascience Inc. at, 1-888-550-6060.

This leaflet was prepared by:

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