

CANDIZOL®
150 mg capsules

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about CANDIZOL

CANDIZOL capsules for oral use contain fluconazole 150 mg with the following excipients: pregelatinized starch, magnesium stearate, and talcum.

Fluconazole is a triazole antifungal agent. Fluconazole inhibits the cytochrome P450-dependent synthesis of ergosterol, which is a vital component of fungal cell membranes.

CANDIZOL is indicated in the treatment of acute or recurrent vaginal and perineal candidiasis.

This medicine may be used to treat other conditions as well.

The way to take CANDIZOL

Take CANDIZOL as directed by your physician. This drug can be taken with or without food.

The recommended dosage of CANDIZOL in acute and recurrent vaginal and perineal candidiasis in adults is 150 mg (1 capsule) as a single dose.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

If you miss a dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Contraindications

This drug is contraindicated in the following conditions:

- Hypersensitivity to fluconazole, or to any of the excipients
- Co-administration of terfenadine, cisapride, astemizole, pimozone, quinidine, and erythromycin

Precautions

- Use with caution in patients with proarrhythmic conditions (structural heart disease, electrolyte abnormalities, and concomitant treatment with certain drugs), and in patients with hypersensitivity to other azoles.
- This drug should be used with caution in patients with liver or renal dysfunction. Patients who develop abnormal liver function tests during therapy should be monitored for the development of more severe hepatic injury. Inform your doctor and discontinue the treatment with fluconazole in case of outbreak of symptoms suggesting a hepatic impairment.
- Patients who develop rashes during treatment with this drug should be monitored closely; inform your doctor and discontinue the treatment if lesions progress.
- Inform your doctor before using this medication in case of pregnancy or lactation.
- Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant use of fluconazole with terfenadine, cisapride, astemizole, pimozone, quinidine, and erythromycin is contraindicated.

Caution or dosage adjustment is needed with hypoglycemic sulfonylureas, coumarin-type oral anticoagulants, phenytoin, cyclosporine, tacrolimus, sirolimus, tofacitinib, zidovudine, rifampin, rifabutin, theophylline, aminophylline, voriconazole, amphotericin B, short-acting benzodiazepines, triazolam, oral contraceptives, hydrochlorothiazide, alfentanil, fentanyl, halofantrine, amitriptyline, nortriptyline, carbamazepine, calcium channel blockers, HMG CoA reductase inhibitors, losartan, celecoxib, NSAIDs, cyclophosphamide, methadone, prednisone, saquinavir, vinca alkaloids, and vitamin A.

Adverse reactions

The most common reported adverse reactions include: headache, nausea, and abdominal pain.

Other reported adverse reactions include: dry mouth, vomiting, diarrhea, dyspepsia, taste perversion, skin rash, elevated liver enzymes, hepatobiliary disorders, asthenia, fatigue, fever, malaise, seizures, dizziness, insomnia, paresthesia, somnolence, vertigo, myalgia, increased sweating, and drug eruption.

Rarely reported adverse reactions include: anaphylactic reactions, QT prolongation, torsade de pointes, leukopenia, including neutropenia and agranulocytosis, thrombocytopenia, tremor, hypercholesterolemia, hypertriglyceridemia, hypokalemia, alopecia, and severe skin reactions.

Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (below 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

CANDIZOL, fluconazole 150 mg, pack of 2 capsules

Issue date: 01/2014

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