

Composition: Each capsule contains Itraconazole pellets eqv. to Itraconazole USP 100mg.

Pharmacology: Itraconazole is an active triazole derivative antifungal. Itraconazole inhibits fungal 14 α -demethylase, resulting in a depletion of ergosterol and disruption of membrane synthesis by fungi.

Indications: Itraconazole Capsules are indicated for the treatment of Vulvovaginal candidiasis, Oropharyngeal candidiasis, Pityriasis versicolor, tinea pedis, tinea cruris, tinea corporis, tinea manuum, Onychomycosis, Histoplasmosis. It is indicated in the treatment of following systematic fungal conditions when first-line systemic anti-fungal therapy is inappropriate or has proved ineffective: Cryptococcosis (including cryptococcal meningitis), Aspergillosis, Candidiasis. It is also used in maintenance therapy in AIDS to prevent relapse of underlying fungal infections and in the prevention of fungal infection during prolonged neutropenia.

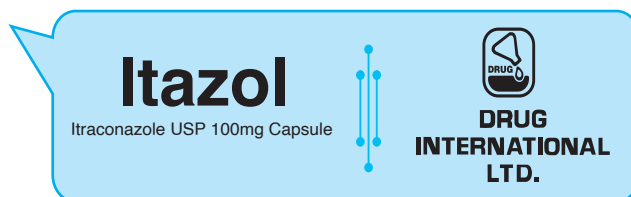
Dosage and administration: This capsule must be taken immediately after a meal for maximal absorption.

• **For Non-Systemic fungal infections:** Vulvovaginal candidiasis: 200mg twice daily for 1 day. Pityriasis versicolor: 200mg once daily for 7 days. Tinea corporis and tinea cruris: 100mg once daily for 15 days or 200mg once daily for 7 days. Tinea pedis and tinea manuum: 100mg once daily for 30 days. Oropharyngeal candidosis: 100mg once daily (200mg once daily in AIDS or neutropenia) for 15 days. Onychomycosis (toenails with or without fingernails involvement): 200mg once daily for 3months. or course (pulse) of 200mg twice daily for 7 days, subsequent courses repeated after 21days interval; fingernails two courses and toenails three courses.

• **For Systemic fungal infections:** Aspergillosis: 200mg once daily for 2-5 months, Increase dose to 200mg twice daily in case of invasive or disseminated disease. Candidiasis: 100-200 mg once daily for 3 weeks-7 months, Increase dose to 200 mg twice daily in case of invasive or disseminated disease. Non-meningeal cryptococcosis: 200mg once daily for 10 weeks. Cryptococcal meningitis: 200mg once daily for 2 months- 6 months. Histoplasmosis: 200mg once daily- twice daily for 8months. Maintenance in AIDS: 200mg once daily until immune recovery. Prophylaxis in neutropenia: 200mg twice daily until immune recovery.

The dose and duration of treatment for systemic fungal disease should be adjusted depending on the clinical response. Or, as directed by the registered physician.

Contraindications: It is contraindicated in patients with known hypersensitivity to itraconazole or any ingredient of the formulation. Co-administration of a



number of CYP3A4 substrates is contraindicated with itraconazole capsules. Itraconazole capsules should not be administered to patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF except for the treatment of life-threatening or other serious infections.

Precautions: Absorption is impaired when gastric acidity is reduced. In patients receiving acid neutralizing medicines (e.g. aluminium hydroxide), these should be administered at least 2 hours after the intake of Itraconazole. The drug should be administered after a full meal. Rarely, cases of hepatitis and jaundice have been reported mainly in patients treated for longer than one month. It is therefore, advised to monitor liver function in patients receiving continuous treatment of more than one month.

Side Effects: Most commonly side effects are: Nausea, abdominal pain, dyspepsia, constipation, headache, dizziness, raised liver enzymes, menstrual disorders, allergic reactions (including pruritus, rash, urticaria and angioedema), hepatitis and cholestatic jaundice, peripheral neuropathy and Stevens-Johnson syndrome reported. On prolonged use hypokalaemia, oedema and hair loss reported.

Use in Pregnancy and Lactation: Not recommended during pregnancy and lactation, unless otherwise indicated by the physician.

Use in Children: The use of Itraconazole capsules in paediatric patients is not recommended unless it is determined that the potential benefit outweighs the potential risks.

Drug Interactions: The drugs like terfenadine, astemizole, cisapride, HMG-CoA reductase inhibitors such as simvastatin, oral midazolam or triazolam should not be given concurrently with Itraconazole. Significant interactions also observed during co-administration of rifampin, phenytoin, phenobarbital, digoxin, and calcium channel blockers.

Overdose: In general, adverse events reported with overdose have been consistent with those reported for itraconazole use.

Storage: Store below 30°C in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

Packing: Each box contains 20 capsules in Alu-Alu blister pack.