

Itra™

Itraconazole

COMPOSITION

Itra™ : Each capsule contains Itraconazole pellets equivalent to Itraconazole INN 100 mg.

PHARMACOLOGY

Itraconazole is an orally active triazole antifungal drug that has demonstrated a broad spectrum of activity and favorable pharmacokinetic profile. Itraconazole inhibits Cytochrome P-450 dependent enzymes resulting in impairment of the biosynthesis of ergosterol, a major component of the cell membrane of yeast and fungal cells. Being integral to the proper functioning of the cell membrane, inhibition of the synthesis of ergosterol leads to a cascade of abnormalities in permeability, membrane bound enzyme activity, and co-ordination of chitin synthesis leading to inhibition of growth, abnormal cell wall formation and accumulation of intracellular lipids and membranous vesicles.

INDICATION

Itra™ (Itraconazole) is used for the treatment of oropharyngeal candidiasis, vulvovaginal candidiasis, pityriasis versicolor, tinea pedis, tinea cruris, tinea corporis, tinea manuum, onychomycosis, histoplasmosis. It is indicated in the treatment of systemic candidiasis, aspergillosis, and cryptococcosis (including cryptococcal meningitis). It is also used for maintenance therapy in AIDS patients to prevent relapse of underlying fungal infections and in the prevention of fungal infection during prolonged neutropenia.

DOSAGE AND ADMINISTRATION

Oropharyngeal candidiasis: 100 mg daily (200 mg daily in AIDS or neutropenia) for 15 days.

Vulvovaginal candidiasis: 200 mg twice daily for 1 day.

Pityriasis versicolor: 200 mg daily for 7 days.

Tinea corporis and tinea cruris: either 100 mg daily for 15 days or 200 mg daily for 7 days.

Tinea pedis and tinea manuum: either 100 mg daily for 30 days or 200 mg twice daily for 7 days.

Onychomycosis: either 200 mg daily for 3 months or course (pulse) of 200 mg twice daily for 7 days, subsequent courses repeated after 21 days interval. Fingernails two courses, toenails three courses.

Systemic infections (aspergillosis, candidiasis and cryptococcosis including cryptococcal meningitis) where other antifungal drugs inappropriate or ineffective: 200 mg once daily, increased in invasive or disseminated disease and in cryptococcal meningitis to 200 mg twice daily.

Histoplasmosis: 200 mg 1-2 times daily. Maintenance in AIDS patients to prevent relapse of underlying fungal infection and prophylaxis in neutropenia when standard therapy is inappropriate: 200 mg once daily, increased to 200 mg twice daily if low plasma Itraconazole concentration is detected.

Child dose: the recommended dose is 3 to 5 mg/kg/day.

ADVERSE EFFECT

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.

CONTRAINDICATION

Itraconazole is contraindicated in patients with known hypersensitivity to the drug or any ingredient in the formulation. Patients who have severe hepatic disease are not advised to take Itraconazole. It is not advisable to use the drug in patients taking rifampin, which appears to initially inhibit and then enhance the metabolism of Itraconazole.

PRECAUTION

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.

DRUG INTERACTION

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.

USE IN PREGNANCY AND LACTATION

Itraconazole is contraindicated in pregnancy. Breast feeding while receiving Itraconazole is not recommended.

STORAGE CONDITION

Protect from light. Store in a cool and dry place.

HOW SUPPLIED

Itra™ : Box containing 24 capsules in Alu-Alu blister.

Manufactured by :



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

TM - Trade Mark.

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