Itra®

Itraconazole

COMPOSITION

Itra® 100 Capsule : Each capsule contains Itraconazole BP 100 mg.
Itra® 200 Tablet : Each film coated tablet contains Itraconazole BP 200 mg.
Itra® Oral Solution: Each ml solution contains Itraconazole BP 10 mg.

PHARMACOLOGY

Itraconazole is an orally active triazole antifungal drug that has demonstrated a broad spectrum of activity & 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 coordination 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.

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

Drugs like terfenadine, astemizole, cisapride, HMG-CoA reductase inhibitors such as simvastatin, oral midazolam or triazolam should not be observed during co-administration of rifampin, phenytoin, phenobarbital, digoxin, and calcium channel blockers.

USE IN PREGNANCY & LACTATION

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

DOSAGE & ADMINISTRATION

Indication	Dose & Duration
Tinea corporis, Tinea cruris	Tablet/Capsule: 100 mg once daily for 15 days or 200 mg once daily for 07 days; Solution: Child 1 month–11 years: 3–5 mg/kg once daily (max. per dose 100 mg) for 15 days. Child 12–17 years: 100 mg once daily for 15 days, alternatively 200 mg once daily for 7 days.
Tinea pedis, Tinea manuum	Tablet/Capsule: 100 mg once daily for 30 days; Solution: Child 1 month–11 years: 3–5 mg/kg once daily (max. per dose 100 mg) for 30 days. Child 12–17 years: 100 mg once daily for 30 days, alternatively 200 mg twice daily for 7 days.
Tinea capitis	Child 1–17 years: 3–5 mg/kg once daily (max. per dose 200 mg) for 2–6 weeks
Onychomycosis	Tablet/Capsule: 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. Solution: Child 1–11 years: 5 mg/kg daily (max. per dose 200 mg) for 7 days, subsequent courses repeated after 21-day intervals; fingernails 2 courses, toenails 3 courses. Child 12–17 years: 200 mg once daily for 3 months, alternatively 200 mg twice daily for 7 days, subsequent courses repeated after 21-day intervals; fingernails 2 courses, toenails 3 courses
Pityriasis versicolor	Tablet/Capsule: 200 mg once daily for 07 days; Solution: Child 1 month–11 years: 3–5 mg/kg once daily (max. per dose 200 mg) for 7 days. Child 12–17 years: 200 mg once daily for 7 days
Oropharyngeal candidiasis	Tablet/Capsule: 100 mg once daily for 15 days, increase dose to 200 mg once daily for 15 days in AIDS or neutropenic patients because of impaired absorption in these groups. Solution: Child 1 month–11 years: 3–5 mg/kg once daily for 15 days; maximum 100 mg per day. Child 12–17 years: 100 mg once daily for 15 days.
Systemic candidiasis	Tablet/Capsule: 100-200 mg once daily for 3 weeks-7 months. Increase dose to 200 mg twice daily in case of invasive or disseminated disease; Solution: Child: 5 mg/kg once daily (max. per dose 200 mg), dose increased in invasive or disseminated disease and in Cryptococcal meningitis, increased to 5 mg/kg twice daily (max. per dose 200 mg)
Vulvovaginal candidiasis	Tablet/Capsule: 200 mg twice daily for 01 day
Aspergillosis	Tablet/Capsule: 200 mg once daily for 2-5 months Increase dose to 200 mg twice daily in case of invasive or disseminated disease; Solution: Child: 5 mg/kg once daily (max. per dose 200 mg), increased to 5 mg/kg twice daily (max. per dose 200 mg), dose increased in invasive or disseminated disease and in cryptococcal meningitis
Systemic cryptococcosis including cryptococcal meningitis	Tablet/Capsule: 200 mg twice daily for 2-6 months; Solution: Child: 5 mg/kg once daily (max. per dose 200 mg), dose increased in invasive or disseminated disease and in cryptococcal meningitis, increased to 5 mg/kg twice daily (max. per dose 200 mg)
Histoplasmosis	Tablet/Capsule: 200 mg once daily-twice daily for 8 months; Solution: Child: 5 mg/kg 1–2 times a day (max. per dose 200 mg)
Maintenance in AIDS	Tablet/Capsule: 200 mg once daily until immune recovery ; Solution: Child: 5 mg/kg once daily (max. per dose 200 mg), then increased to 5 mg/kg twice daily (max. per dose 200 mg), dose increased only if low plasma Itraconazole concentration
Prophylaxis in neutropenia	Tablet/Capsule: 200 mg once daily until immune recovery; Child: 2.5 mg/kg twice daily, to be started before transplantation or before chemotherapy (taking care to avoid interaction with cytotoxic drugs) and continued until neutrophil count recovers, safety and efficacy not established

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.

STORAGE CONDITION

Store below 25° C. Do not freeze. Keep all medicines out of reach of children.

HOW SUPPLIED

Itra® 100 Capsule : Each box containing 28 capsules in Alu-Alu blister pack.
Itra® 200 Tablet: Each box containing 18 tablets in Alu-Alu blister pack.
Itra® Oral Solution: Each bottle contains 100 ml solution with a measuring cup.

Manufactured by-

SQUARE
PHARMACEUTICALS PLC.
Bangladesh