Itra® Nova 65

Itraconazole BP 65 mg

COMPOSITION
Itra® Nova 65: Each capsule contains Super Bioavailable Itraconazole BP 65 mg.

PHARMACOLOGY
SUBA (Super Bioavailability) is a novel technology for enhancing the bioavailability of poorly soluble drugs. This technology utilizes a solid dispersion of drug in a polymer that improves the dissolution of poorly soluble drugs compared to their normal crystalline form. SUBA 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® Nova 65 (SUBA Itraconazole) is used for the treatment of oropharyngeal candidiasis, vulvovaginal candidiasis, pityriasis versicolor, tinea pedis, tinea cruris, tinea corporis, tinea manuum, onychomycosis and 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 & ADMINISTRATION
For non-systemic fungal disease:

Indication	Dose & Duration
Vulvovaginal candidiasis	130 mg (2 x 65 mg capsules) twice daily for 01 day
Pityriasis versicolor	130 mg (2 x 65 mg capsules) twice daily for 07 days
Tinea corporis and tinea cruris	65 mg once daily for 15 days or 130 mg (2 x 65 mg capsules) once daily for 07 days
Tinea pedis and tinea manuum	65 mg once daily for 30 days
Oropharyngeal Candidiasis	65 mg once daily for 15 days, increase dose to 130 mg (2 x 65 mg capsules) once daily for 15 days in AIDS or neutropenic patients because of impaired absorption in these groups
Onychomycosis (toenails with or without fingernail involvement)	Either 130 mg (2 x 65 mg capsules) once daily for 3 months or course (pulse) of 130 mg (2 x 65 mg capsules) twice daily for 7 days, subsequent courses repeated after 21 day's interval. Fingernails two courses, toenails three courses.

For systemic fungal disease:

Aspergillosis	130 mg (2 x 65 mg capsules) once daily for 2-5 months. Increase dose to 130 mg (2 x 65 mg capsules) twice daily in case of invasive or disseminated disease
Candidiasis	65-130 mg once daily for 03 weeks-07 months. Increase dose to 130 mg (2 x 65 mg capsules) twice daily in case of invasive or disseminated disease
Non-meningeal Cryptococcosis	130 mg (2 x 65 mg capsules) once daily for 10 weeks
Cryptococcal Meningitis	130 mg (2 x 65 mg capsules) twice daily for 2-6 months
Histoplasmosis	130 mg (2 x 65 mg capsules) once daily-twice daily for 8 months
Maintenance in AIDS	130 mg (2 x 65 mg capsules) once daily until immune recovery
Prophylaxis in neutropenia	130 mg (2 x 65 mg capsules) once daily until immune recovery

* The dose and duration of treatment for systemic antifungal disease should be adjusted depending on the clinical response.

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, edema 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.

WARNING & 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
Store below 25°C, in a dry place. Keep all medicines out of reach of children.

HOW SUPPLIED
Itra® Nova 65: Each box contains 30 capsules in Alu-Alu blister pack.

Manufactured by
SQUARE PHARMACEUTICALS PLC.
Bangladesh

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