

Composition

Itratec SB 65 Capsule: Each capsule contains Itraconazole BP 65 mg. using Super Bioavailable Formulation.

Itratec SB 100 Capsule: Each capsule contains Itraconazole BP 100 mg. using Super Bioavailable Formulation.

Itratec 100 ml Oral Solution: Each 5 ml Oral Solution contains Itraconazole USP 50 mg.

Pharmacology

SUBA (Super Bioavailable Formulation) is a novel technology for enhancing the bioavailability of poorly soluble drugs. This formulation utilizes a solid dispersion of drug in a polymer that improves the dissolution profile. SUBA-Tech Itraconazole (Itratec SB) 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.

Indications

Itratec SB Capsule: Tinea corporis, Tinea cruris, Tinea pedis, Tinea manuum, Vulvovaginal candidiasis, Fungal keratitis, Pityriasis versicolor, Oropharyngeal candidiasis, Onychomycosis, Histoplasmosis, Systemic Infections: Aspergillosis, Candidiasis and Cryptococcal infection when other drugs are ineffective. Antifungal prophylaxis: To prevent systemic fungal infection in severely neutropenic patients.

Itratec Oral Solution: It is indicated for the treatment of Oropharyngeal Candidiasis, Tinea capitis, Tinea pedis and Tinea Manuum, Tinea corporis and Tinea cruris, Pityriasis versicolor & Onychomycosis.

Dosage & Administration

Itratec SB: 65-100 mg once or twice daily for all type of systemic and non-systemic fungal infections or as directed by the physician.

Itratec SB Capsule:

Indications		Dose & Duration
Non-systemic fungal infections	Vulvovaginal candidiasis	100 mg twice daily for 01 day
	Pityriasis versicolor	100 mg twice daily for 07 days
	Tinea corporis and tinea cruris	65 mg once daily for 15 days, 100 mg once daily for 07 days
	Tinea pedis and tinea manuum	65 mg once daily for 30 days
	Onychomycosis (toenails with or without fingernail involvement)	100 mg once daily for 3 months or course (pulse) of 100 mg twice daily for 7 days, subsequent course repeated after 21 day's interval. Fingernails two courses, toenails three courses
Systemic fungal infections	Aspergillosis	100 mg once daily for 2-5 months. Increase dose to 100 mg twice daily in case of invasive or disseminated disease
	Candidiasis	65-100 mg once daily for 03 weeks-07 months. Increase dose to 100 mg twice daily in case of invasive or disseminated disease

Itratec Oral Solution:

Indications	Age	Duration	Maximum dose
Oropharyngeal candidiasis	1 month to 11 years	15 days	100 mg/day
Tinea capitis	1 to 17 years	2 to 6 weeks	100 mg/day
Tinea pedis and Tinea Manuum	1 month to 11 years	30 days	100 mg/day
Tinea corporis and Tinea cruris	1 month to 11 years	15 days	100 mg/day
Pityriasis versicolor	1 month to 11 years	7 days	200 mg/day
Onychomycosis	1 month to 11 years	7 days*	200 mg/day

Dose: 3-5 mg/kg/day

*In case of Onychomycosis, subsequent courses repeated after 21-days interval; fingernails 2 courses, toenails 3 courses.

Contraindication

The drug is contraindicated in patients with known history of hypersensitivity to it. The drug is also contraindicated in pregnant women and patients with known severe hepatic disease. It is also contraindicated with Rifampicin therapy.

Warnings and Precautions

Hepatic enzyme value should be monitored in patients with pre-existing hepatic function abnormalities .It should also be monitored periodically in all patients receiving continuous treatment for more than one month or at any time a patient develops sign and symptoms suggestive liver dysfunction.

Side Effects

Nausea, abdominal pain, dyspepsia, constipation, headache, dizziness, raised liver enzymes, hepatitis, cholestatic jaundice , peripheral neuropathy have been reported.

Use in Pregnancy and Lactation

Not recommended during pregnancy & lactation, unless otherwise indicated by physician.

Use in Children & Adolescents

Capsule: The efficacy and safety of Itraconazole capsule have not been established in paediatric patients and adolescents.

Oral Solution: Safe for paediatric patients (from 1 month age & above).

Drug Interaction

Itraconazole inhibits the metabolism of Cyclosporine and Warfarin. Interaction with Terfenadine, Phenobarbitone, Midazolam has been reported.

Overdose

There is no experience of overdosage with Itraconazole.

Storage

Itratec SB Capsule: Store below 25°C, keep in a dry place and protect from light.

Itratec Oral Solution: Store below 25°C, keep in a dry place and protect from light. Do not freeze.

Keep all medicines out of the reach of children.

Packaging

Itratec SB 65 Capsule: Each box contains 3X10's capsules in Alu-Alu blister pack and an insert.

Itratec SB 100 Capsule: Each box contains 5X6's capsules in Alu-Alu blister pack and an insert.

Itratec 100 ml Oral Solution: Each bottle contains 100 ml oral solution, measuring cup and an insert.

Manufactured by



Ziska Pharmaceuticals Ltd.

Kaliakoir, Gazipur, Bangladesh

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