

Composition

Truzole SB 65 capsule: Each capsule contains Itraconazole BP 65 mg.

Truzole 100 capsule: Each capsule contains Itraconazole BP 100 mg as pellets.

Truzole 200 tablet: Each film coated tablet contains Itraconazole BP 200 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 co-ordination of chitin synthesis leading to inhibition of growth, abnormal cell wall formation and accumulation of intracellular lipids and membranous vesicles.

Indication

Itraconazole is used for the treatment of-

- Tinea infections (Tinea pedis, Tinea cruris, Tinea corporis, Tinea manuum)
- Oropharyngeal candidiasis
- Vulvovaginal candidiasis
- Pityriasis versicolor
- Onychomycosis
- Histoplasmosis
- Fungal keratitis
- Systemic infections: Candidiasis, Aspergillosis and Cryptococcosis (including cryptococcal meningitis)
- Antifungal prophylaxis: To prevent systemic fungal infection in severely neutropenic patients.

Dose & Administration

a) *Route of administration:* Oral

For non-systemic fungal disease:

Indication	Dose & Duration
Vulvovaginal candidiasis	200 mg twice daily for 01 day
Pityriasis versicolor	200 mg once daily for 07 days
Tinea corporis, Tinea cruris	100 mg once daily for 15 days or 200 mg once daily for 7 days
Tinea pedis, Tinea manuum	100 mg once daily for 30 days
Oropharyngeal candidiasis	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.
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.

For systemic fungal disease:

Indication	Dose & Duration
Aspergillosis	200 mg once daily for 2-5 months. Increase dose to 200 mg 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	200 mg once daily for 10 weeks
Cryptococcal meningitis	200 mg twice daily for 2-6 months
Histoplasmosis	200 mg once daily - twice daily for 8 months
Maintenance in AIDS	200 mg once daily until immune recovery
Prophylaxis in neutropenia	

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

Contra-indication

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.

Warning & Precaution

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

Side effects

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

b) *Rare:* Stevens-Johnson syndrome. On prolonged use hypokalaemia, oedema and hair loss reported.

Use in Pregnancy & Lactation

a) *Use in Pregnancy:* Itraconazole is contraindicated in pregnancy.

b) *Use in Lactation:* Breast feeding while receiving Itraconazole is not recommended.

Use in Children & adolescent

a) *Children:* The efficacy and safety of the Itraconazole capsule have not been established in pediatric patients.

b) *Geriatric Use:* There are inadequate data on Itraconazole in elderly. It's use is to be recommended, if the potential benefits outweigh the risks.

Drug interaction

a) *With Medicine:* Itraconazole inhibits the metabolism of Cyclosporine and Warfarin. Interaction with Terfenadine, Phenobarbitone and Midazolam has been reported.

b) *With Food & Others:* Itraconazole is for oral administration and must be taken immediately after a meal for maximum absorption.

Overdose

There is no experience of over dosage with Itraconazole.

Storage

Store below 30°C. Protect from light & moisture. Keep all medicines out of reach of children.

Packing

Truzole SB 65 capsule: Each Box contains 30 (3x10's) capsules in blister pack.

Truzole 100 capsule: Each Box contains 30 (3x10's) capsules in blister pack.

Truzole 200 tablet: Each Box contains 20 (2x10's) tablets in blister pack.