

Composition

Eloza SB Capsule: Each capsule contains Itraconazole BP 65 mg in Superbioavailable (SUBA) form.

Pharmacology

Super Bioavailable (SUBA) Technology is a specialized pharmaceutical delivery system that enhances the bioavailability (absorption rate in the body) of drugs. It is specifically designed for poorly soluble drugs, helping them to be better absorbed and increasing their effectiveness. Itraconazole formulated with SUBA technology (**Eloza SB**) is absorbed more efficiently compared to conventional Itraconazole, leading to better control of fungal infections. Additionally, it reduces side effects and provides effective results even at lower doses.

Itraconazole inhibits Cytochrome P450 dependent enzymes resulting in impairment of the biosynthesis of ergosterol, a major component of the cell membrane of yeast and fungal cells. 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.

Indications

Eloza SB 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

Itraconazole must be administered with food. Swallow the capsule whole without chewing, crushing or breaking it.

For non-systemic fungal diseases:

Indication	Dose and Duration
Tinea Corporis & Tinea Cruris	65 mg capsule once daily for 15 days or twice daily for 7 days.
Tinea Pedis & Tinea Manuum	65 mg capsule daily for 30 days.
Vulvovaginal Candidiasis	130 mg (2x65 mg capsules) twice daily for 1 day.
Pityriasis Versicolor	130 mg (2x65 mg capsules) twice daily for 7 days.
Oropharyngeal Candidiasis	65 mg capsule once daily for 15 days, increase dose to 65 mg twice daily for 15 days.
Onychomycosis (toenails with or without fingernail involvement)	Either 65 mg capsule twice daily for 3 months or course (pulse) of 130 mg (2x65 mg capsules) twice daily for 7 days; subsequent courses repeated after 21 days interval. Fingernails are two courses, toenails are three courses.

For systemic fungal diseases:

Indication	Dose and Duration
Aspergillosis	65 mg capsule twice daily for 2-5 months. Increase dose to 130 mg (2x65 mg capsules) twice daily in case of invasive or disseminated disease.
Candidiasis	65-130 mg once daily for 3 weeks -7 months. Increase dose to 65 mg twice daily in case of invasive or disseminated disease.
Non- meningeal Cryptococcosis	65 mg capsule twice daily for 10 weeks.
Cryptococcal Meningitis	130 mg (2x65 mg capsules) twice daily for 2-6 months.
Histoplasmosis	130 mg (2x65 mg capsules) once or twice daily for 8 months.
Prophylaxis in neutropenia	65 mg capsule twice daily until immune recovery.
Maintenance in AIDS	65 mg capsule twice daily until immune recovery.

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

Contraindications

Itraconazole is contraindicated in patients with known hypersensitivity to the drug. Co-administration of certain drugs that are metabolized by human CYP3A4 substrates are contraindicated with Itraconazole. Co-administration with colchicine, fesoterodine and solifenacin are contraindicated in subjects with varying degrees of renal or hepatic impairment.

Warning and Precaution

Physicians should carefully review the risks and benefits of Itraconazole for patients with evidence of Congestive Heart Failure. If clinical signs or symptoms of hepatotoxicity develop that are consistent with liver disease, discontinue treatment and perform testing for liver disease. Concomitant administration of the drugs like Pimozide, Methadone, or Quinidine with oral Itraconazole is contraindicated.

Side Effects

Most common side effects of Itraconazole are nausea, rash, vomiting, swelling, headache, diarrhea, fatigue, fever, itching, hypertension, abnormal hepatic function, abdominal pain, dizziness, loss of appetite, decreased libido, somnolence etc.

Use in Pregnancy and Lactation

Itraconazole is contraindicated in pregnancy. Breastfeeding while receiving Itraconazole is not recommended.

Use in Children

The efficacy and safety of Itraconazole have not been established in pediatric patients.

Use in Geriatric Patients

Itraconazole should be used with care in elderly patients.

Drug Interaction

Itraconazole is mainly metabolized through CYP3A4. Other substances that either share this metabolic pathway or modify CYP3A4 activity may influence the pharmacokinetics of Itraconazole. 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 are also observed during co-administration of Rifampin, Phenytoin, Phenobarbital, Digoxin, and Calcium channel blockers.

Overdose

Itraconazole is not removed by dialysis. In the event of accidental overdosage, supportive measures should be employed. Activated charcoal may be given if considered appropriate.

Storage

- Store below 30°C & dry place, protect from light.

- Keep out of the reach of children.

Packing

Eloza SB Capsule: Each box contains 30 capsules in alu-alu blister pack.

Manufactured by:



ARISTOPHARMA LTD.

Shampur-Kadamtali I/A, Dhaka-Bangladesh