

Ketotab

(Ketoconazole USP)

Composition:

Ketotab Tablet: Each tablet contains Ketoconazole USP 200 mg.

Descriptions:

Ketoconazole is a synthetic imidazole derivative with a potent activity against dermatophytes, yeasts and other pathogenic fungi, after oral administration.

Indications:

1. Treatment of superficial and deep mycoses : Infections of the skin, hair and nails by dermatophytes and/or yeasts (dermatomycosis, onychomycosis, perionyxia, pityriasis versicolor, chronic mucocutaneous candidiasis etc.) especially when topical treatment is difficult or not very effective, owing to involvement of large skin surfaces or to lesions affecting deeper dermal layers, nails and hairs ; Yeast infection of the mouth (oral thrush, perleche) and the gastrointestinal tract ; Vaginal candidiasis, especially chronic recurrent cases or cases responding poorly to topical treatment ; Systemic mycotic infections such as systemic candidiasis, paracoccidioidomycosis, histoplasmosis, coccidioidomycosis etc.
2. Maintenance treatment to prevent recurrence in systemic mycotic infections and in chronic mucocutaneous candidiasis.
3. Prophylactic treatment to prevent mycotic infection in patients with reduced host defenses, e.g., patients with cancer, organ transplant and burns.

Dosage & Administration:

Vaginal candidiasis: 1 tablet b.i.d. for 5 days.

All other indications: Adults: 1 tablet (200 mg) once daily until at least one week after the symptoms have disappeared and the cultures have become negative.

Children: 3 to 5 mg/kg/day.

Indication	Duration of Treatment
Pityriasis versicolor	1 to 6 weeks
Dermatomycoses	2 to 8 weeks
Onychomycoses	1 to 12 months
Mycoses of hair and scalp	1 to 2 months
Chronic mucocutaneous candidiasis	1 to 12 months
Oral mycoses	5 to 10 days
Systemic candidiasis, Paracoccidioidomycosis, histoplasmosis	1 to 2 months
and other systemic mycosis	1 month to 2 years

Remark :

Ketoconazole should be taken at meal times for maximal resorption. Because resorption depends on intact gastric activity, the concomitant treatment with agents that reduce gastric secretion (anticholinergic drugs, antacids, H₂ blockers) should be avoided. When indicated, such drugs should be taken not earlier than two hours after ketoconazole. If clinical responsiveness is insufficient within the expected time, the dose of ketoconazole may be doubled (400 mg once daily)

Side Effects:

Ketoconazole is very well tolerated. Nausea and itching may occasionally occur. In some patients, an idiosyncratic liver reaction may occur. (One in every 10,000 People)

Precautions:

The liver function of the patients should be monitored during and after treatment.

Contraindications:

Ketoconazole is contraindicated in pregnancy and in patients with acute liver pathology.

Use in Pregnancy & Lactation:

Use in Pregnancy: Category: C. There is no adequate and well controlled studies in pregnant women. Ketoconazole Tablets should not be used during pregnancy and lactation.

Drug Interaction:

Ketoconazole may influence the pharmacokinetics properties of others drugs or others drugs may influence the pharmacokinetics of ketoconazole. This interaction studies have only been performed in adults from study in pediatric patients is unknown.

Storage: Store in a cool and dry place, protect from light and moisture

Presentation

Ketotab Tablet: Each box contains 4x10 tablets in blister packing.

**Manufactured by**

The **IBN SINA** Pharmaceutical Industry Ltd.
Shafipur, Kaliakoir, Gazipur, Bangladesh.