KETOTAB

KETOCONAZOLE USP

Compositions:
Each tablet contains Ketoconazole BP 200 mg.

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

Dosage And 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 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)

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

Warning And Precaution:
The liver function of the patients should be monitored during and after treatment.

Side Effects:
Ketoconazole is very well tolerated. Nausea and itching may occasionally occur. In some patients, an idiosyncratic liver reaction may occur.

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

Drug Interaction:
Ketoconazole is mainly metabolized through CYP3A4. Other substances that either share this metabolic pathway or modify CYP3A4 activity may influence the pharmacokinetics of ketoconazole. Similarly, ketoconazole may modify the pharmacokinetics of other substances that share this metabolic pathway. Ketoconazole is a potent CYP3A4 inhibitor and a P-glycoprotein inhibitor. When using concomitant medication, the corresponding label should be consulted for information on the route of metabolism and the possible need to adjust dosages. Interaction studies have only been performed in adults. The relevance of the results from these studies in pediatric patients is unknown.

Overdosage:
In the event of acute accidental overdose, treatment consists of supportive and symptomatic measures. Within the first hour after ingestion, activated charcoal may be administered.

Storage:
Store in cool and dry place (below 30°C), protect from light. Keep out of reach of children.

Packing:
Each box contains 4X10 tablets in blister packing.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.