

Ketoral[®]

Ketoconazole BP

Ketoral[®] (Ketoconazole) is a synthetic imidazole derivative with a potent activity against dermatophytes, yeasts and other pathogenic fungi, after oral administration.

COMPOSITION

Ketoral[®] Tablet: Each tablet contains ketoconazole BP 200 mg.

INDICATION

1. Treatment of superficial and deep mycoses :

Infections of the skin, hair and nails by dermatophytes and/or yeasts (dermatomycosis, onychomycosis, perionyxis, 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 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 : 1 to 2 months

Paracoccidioidomycosis, histoplasmosis 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).

ADVERSE REACTIONS

Ketoconazole is very well tolerated. Nausea and itching may occasionally occur. In some patients, an idiosyncratic liver reaction may occur (incidence 1 : 10,000).

WARNINGS

In patients with a previous history of liver disease, liver enzyme levels should be monitored during treatment. When patients develop symptoms indicative of liver reaction, such as nausea or fatigue, accompanied with pale faeces, dark urine or jaundice, **Ketoral[®]** therapy should be stopped immediately.

CONTRAINDICATIONS

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

STORAGE CONDITION

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

HOW SUPPLIED

Ketoral[®] Tablet : Box containing 40 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH