Kezona®

Ketoconazole USP Tablet

DESCRIPTION

Kezona® is a preparation of Ketoconazole. Ketoconazole is a synthetic imidazole dioxolane derivative with a fungicidal or fungistatic activity against dermatophytes, yeasts (*Candida, Malassezia, Torulopsis, Cryptococcus*), dimorphic fungi and eumycetes. Less sensitive are: *Aspergillus spp., Sporothrix schenckii*, some *Dematiaceae, Mucor spp.* and other *phycomycetes*, except *Entomophthorales*. Ketoconazole inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane.

INDICATIONS

Infections of the skin, hair, and mucosa, induced by dermatophytes and/or yeasts that cannot be treated topically because of the site or the extent of the lesion or deep infection of the skin.

- Dermatophytosis
- Pityriasis versicolor
- Pityrosporum folliculitis
- Cutaneous candidosis
- Chronic mucocutaneous candidosis
- Oropharyngeal and esophageal candidosis
- Chronic, recurrent vaginal candidosis

Systemic fungal infections: Ketoconazole does not penetrate well in the CNS. Therefore, fungal meningitis should not be treated with oral Ketoconazole.

- Paracoccidioidomycosis
- Histoplasmosis
- Coccidioidomycosis
- Blastomycosis

DOSAGE AND ADMINISTRATION

- **Adults:** One tablet once daily with a meal. When no adequate response is obtained with this dose, the dose should be increased to 2 tablets once daily.
- **Adults with vaginal candidosis:** Two tablets once daily with a meal.
- **Children:** Children weighing from 15 to 30 kg: half a tablet once daily with a meal. Children weighing more than 30 kg: same as for adults.

SIDE EFFECTS

- Nausea
- Headache
- Diarrhea
- Abdominal pain
- Vomiting

CONTRAINDICATIONS

- In patients with known hypersensitivity to Ketoconazole or any of the exipient.
- In patients with acute or chronic liver disease.
- Coadministration of number of CYP3A4 substate is contraindicated with Ketoconazole tablet.

PRECAUTIONS AND WARNINGS

Because of the risk for serious hepatotoxicity, Ketoconazole tablets should be used only when the potential benefits are considered to outweigh the potential risks, taking into consideration the availability of other effective antifungal therapy. Assess liver function, prior to treatment to rule out acute or chronic liver disease, and monitor at frequent and regular intervals during treatment, and at the first signs or symptoms of possible hepatotoxicity.

DRUG INTERACTION

Drugs that reduce the gastric acidity (e.g. acid neutralizing medicines such as aluminium hydroxide, or acid secretion suppressors such as H2-receptor antagonists and proton pump inhibitors) impair the absorption of Ketoconazole from Ketoconazole tablets. These drugs should be used with caution when coadministered with Ketoconazole tablets.

PREGNANCY AND LACTATION

Pregnancy Category C. There is limited information on the use of Ketoconazole tablets during pregnancy. Animal studies have shown reproductive toxicity. The potential risk to humans is unknown. Therefore, Ketoconazole tablets should not be used during pregnancy unless the potential benefit to the mother outweighs the possible risk to the foetus.

Since Ketoconazole is excreted in the milk, mothers who are under treatment should not breast-feed.

PHARMACEUTICAL PRECAUTIONS

Store below 30 °C temperature, away from light and wet place. Keep out of reach of children.

PACKAGING

Kezona® Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Ketoconazole USP 200 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LIMITED

TONGI, GAZIPUR, BANGLADESH

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