



treatment of cutaneous candidiasis caused by *Candida* spp. and in the treatment of seborrheic dermatitis.

## **CONTRAINDICATIONS**

Ketoconazole Cream 2% is contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation.

## **WARNINGS**

Ketoconazole Cream 2% is not for ophthalmic use.

Ketoconazole Cream 2% contains sodium sulfite anhydrous, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

## **PRECAUTIONS**

### **General:**

If a reaction suggesting sensitivity or chemical irritation should occur, use of the medication should be discontinued. Hepatitis (1:10,000 reported incidence) and, at high doses, lowered testosterone and ACTH induced corticosteroid serum levels have been seen with orally administered ketoconazole; these effects have not been seen with topical ketoconazole.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility:**

A long-term feeding study in Swiss Albino mice and in Wistar rats showed no evidence of oncogenic activity. The dominant lethal mutation test in male and female mice revealed that single oral doses of ketoconazole as high as 80 mg/kg produced no mutation in any stage of germ cell development.

The Ames' Salmonella microsomal activator assay was also negative.

### **Pregnancy: Teratogenic effects: Pregnancy Category C:**

Ketoconazole has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given orally in the diet at 80 mg/kg/day, (10 times the maximum recommended human oral dose). However, these effects may be related to maternal toxicity, which was seen at this and higher dose levels. There are no adequate and well-controlled studies in pregnant women. Ketoconazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### **Nursing Mothers:**

It is not known whether Ketoconazole Cream 2% administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, a decision should be

made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

**Pediatric Use:**

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS**

During clinical trials 45 (5.0%) of 905 patients treated with Ketoconazole Cream 2% and 5 (2.4%) of 208 patients treated with placebo reported side effects consisting mainly of severe irritation, pruritus and stinging. One of the patients treated with Ketoconazole Cream developed a painful allergic reaction.

**DOSAGE AND ADMINISTRATION**

Cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis and tinea (pityriasis) versicolor: It is recommended that Ketoconazole Cream 2% be applied once daily to cover the affected and immediate surrounding area. Clinical improvement may be seen fairly soon after treatment is begun; however, candidal infections and tinea cruris and corporis should be treated for two weeks in order to reduce the possibility of recurrence. Patients with tinea versicolor usually require two weeks of treatment. Patients with tinea pedis require six weeks of treatment.

*Seborrheic dermatitis:* Ketoconazole Cream 2% should be applied to the affected area twice daily for four weeks or until clinical clearing. If a patient shows no clinical improvement after the treatment period, the diagnosis should be redetermined.

**PRESENTATION:**

Ketoconazole Cream 2% is supplied as follows:

15 gram tube

**STORAGE:**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it in cool & dark place. DO NOT FREEZE.

For further information, please contact:

**Market Planning Department**

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