

KETOCONAZOLE (Topical)

Introduction

Indications

Accepted

Tinea corporis 23, 25 (treatment) or

Tinea cruris 23, 25 (treatment) 7 Ketoconazole cream is indicated as a primary agent 7 in the topical treatment of tinea corporis (ringworm of the body) and tinea cruris (ringworm of the groin; jock itch) caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum* (*Acrothesium floccosum*). 1, 6, 9, 13, 15, 18, 19, 21, 23, 25

Tinea pedis 23, 25 (treatment) 7 Ketoconazole cream is indicated as a primary agent in the topical treatment of tinea pedis (athlete's foot). 18, 19, 23, 25

Pityriasis versicolor 25 (treatment) 7 Ketoconazole cream and ketoconazole 2% shampoo are indicated as primary agents 7 in the topical treatment of pityriasis versicolor (tinea versicolor; "sun fungus") caused by *Malassezia furfur* (*Pityrosporon orbiculare*). 1, 6, 9, 13, 15, 17, 18, 19, 21, 23, 24, 25

Candidiasis, cutaneous 23, 25 (treatment) 7 Ketoconazole cream is indicated as a primary agent 7 in the topical treatment of cutaneous candidiasis caused by *Candida* species. 6, 9, 15, 18, 19, 21, 23, 25

Dermatitis, seborrheic (treatment) 23, 25, 26 or

Dermatitis, seborrheic (prophylaxis) 26 7 Ketoconazole cream and [ketoconazole 2% shampoo] 26 are indicated in the treatment of seborrheic dermatitis. 9, 10, 13, 15, 18, 19, 21, 23, 25, 26
[Ketoconazole 2% shampoo] is indicated in the prophylaxis of seborrheic dermatitis. 26

Dandruff (treatment) or

Dandruff (prophylaxis) 7 Ketoconazole shampoo 1% 27 and [ketoconazole shampoo 2%] 26 are indicated in the treatment and prophylaxis of the flaking, scaling, and itching associated with dandruff. 12, 14, 16, 20, 22, 26, 27

[Paronychia (treatment)] * 6

[Tinea barbae (treatment)] * or 6

[Tinea capitis (treatment)] * 6 7 Ketoconazole cream is used as a primary agent in the topical treatment of paronychia. 7, 13 Ketoconazole cream is used as a secondary agent 7 in the topical treatment of tinea barbae and tinea capitis. 6

Precautions to Consider

Cross-sensitivity and/or related problems

Persons sensitive to miconazole or other imidazoles may be sensitive to ketoconazole also. 13, 25

Carcinogenicity

A long-term feeding study in Swiss albino mice and Wistar rats has shown no evidence of carcinogenicity. 1, 9, 15, 23, 24

Mutagenicity

The dominant lethal mutation test in male and female mice, given single oral doses of ketoconazole as high as 80 mg per kg of body weight (mg/kg), has shown no mutations at any stage of germ cell development. The Ames Salmonella microsomal activator assay has also shown negative results. 1, 9, 15, 23, 24

Pregnancy/Reproduction

Pregnancy¾Ketoconazole crosses the placenta. Adequate and well-controlled studies in humans have not been done. 23, 24

Studies in rats, given oral doses of 80 mg/kg per day (10 times the maximum recommended human dose [MRHD]), have shown ketoconazole to be teratogenic, causing syndactyly and oligodactyly. 23, 24 However, these effects may be related to maternal toxicity, which was seen at this dose level. 23, 24

FDA Pregnancy Category C. 1, 2, 9, 15, 23, 24

Breast-feeding

It is not known whether ketoconazole cream 23 , applied topically on a regular basis, is absorbed systemically in sufficient amounts to be distributed into breast milk in detectable quantities. 9, 15, 23 However, no systemic absorption was detected following a single application of ketoconazole cream 23 to the chest, back, and arms of healthy volunteers. 23 In addition, ketoconazole shampoo was not detected in plasma after chronic shampooing. 24 Therefore, topical ketoconazole is unlikely to be distributed into breast milk in significant amounts or to cause adverse effects in the nursing infant. 7

Pediatrics

No information is available on the relationship of age to the effects of this medicine in pediatric patients. Safety and efficacy have not been established 15, 23, 24.

Geriatrics

No information is available on the relationship of age to the effects of this medicine in geriatric patients.

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¾ not necessarily inclusive (>> = major clinical significance).

Risk-benefit should be considered when the following medical problems exist

Sensitivity to topical ketoconazole 25

Sensitivity to sulfites present in ketoconazole cream 23

Side/Adverse Effects

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:

Those indicating need for medical attention

For the cream or shampoo¾Incidence less frequent

Itching, stinging, or irritation not present before therapy 23, 24

For the cream¾Incidence rare

Contact dermatitis 23 (skin rash)

Those indicating need for medical attention only if they continue or are bothersome

For the shampoo¾Incidence less frequent

Dry skin 24; dryness or oiliness of the hair and scalp 24

For the shampoo¾Incidence rare

Increase in normal hair loss 24