[싱가포르][말레이시아]
안타나졸크림 설명서

Size : 120 x 195 (mm)

수정사항

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Topical Fungicides

ANTANAZOL Cream

ANTANAZOL Cream contains the broadspectrum synthetic antifungal agent, ketoconazole 2%.
ANTAZAZOL is highly active against most pathogenic fungi, including dermatophytes and yeasts.

■ DESCRIPTION

ANTANAZOL Cream is a white , odorless cream which comes in 10g aluminum tube placed in a printed box with a package insert.

■ COMPOSITION

ANTANAZOL Cream 1g contains 20mg of Ketoconazole, 75mg of Propylene glycol, 0.2mg of Propyl paraben and 1mg of Methyl paraben.

■ ACTION

1. Broadspectrum antifungal activity
   ANTANAZOL is active against most pathogenic fungi and impairs the synthesis of ergosterol, which is a vital component of fungal cell membrane.
2. Low toxicity and adverse reactions
   Topically applied ANTANAZOL appears to have a low order of adverse reactions (dermal irritation, allergy and photosensitization etc.) and toxicity.
3. Good absorption
   ANTANAZOL is commercially available as a cream in an aqueous base. After a topical application, ANTANAZOL is fully active.

■ PHARMACOLOGY

The antifungal properties of ketoconazole were investigated both in vitro and in vivo. The antifungal potency of ketoconazole in vitro was studied in Sabouraud's broth for 715 fungal strains belonging to 85 species and several strains were tested in other media, including Eagle's minimal essential medium. Ketoconazole is highly active in vitro and possesses broad-spectrum activity. Its in vitro activity is largely dependent on the medium used. Ketoconazole's activity is increased in medium enriched with serum and in Eagle's minimal essential medium. Ketoconazole is very potent in the topical treatment of skin dermatophytosis, skin candidiasis, and in vaginal candidiasis of laboratory animals. Ketoconazole is superior to griseofulvin in the oral treatment of skin dermatophytosis. Furthermore, ketoconazole is orally highly active in skin candidiasis in various animal species. In systemic candidiasis and in disseminated dermatophytosis in guinea pigs cure with oral ketoconazole is achieved. No side effects are observed.

■ PHARMACOKINETICS

<Absorption> Approximately 1 to 2 hours after a single 200mg dose, the serum concentration ranges from 1.6 to 6.9mcg / ml and can be maintained with a single daily dose. Relative bioavailability of the tablet formulation is about 80% (Huan et al, 1986). Controversy exists as to whether higher serum levels are achieved if the drug is given without food (Lelawongs et al, 1988). The absence of gastric hydrochloric acid will lead to poor absorption of ketoconazole. Thus, especially in the elderly and in patients with AIDS, who frequently have achlorhydria, serum levels of ketoconazole may not attain expected levels. Since bioavailability depends on gastric acidity, glumatic acid capsules may provide an effective, convenient method of enhancing ketoconazole's absorption in patients with reduced gastric acidity (Lelawongs et al, 1988). Anticholinergic agents H2 blocking agents(eg. cimetidine, ranitidine) should be avoided . Antacids may not interfere with absorption if they are given no less than 2 hours after ketoconazole.

<Metabolism> Extensive hepatic degradation by microsomal enzymes occurs, and little active drug is excreted in the bile. Only 2% to 4% of a dose is eliminated unchanged in the urine. Dose-dependent kinetics were observed in humans with doses of 200, 400 and 800mg ; the cause remains to be determined (Huang et al, 1986). Metabolic enzyme induction probably does not occur at doses of 400mg per day in humans (Blyden et al, 1986)

<Distribution> Ketoconazole is 95% to 99% bound to plasma proteins, principally albumin. Concentrations in the cerebrospinal fluid are only 1% to 4% of those in the serum at usual therapeutic doses. Only negligible concentrations occur in the peritoneal fluid of patients undergoing peritoneal dialysis.

<Elimination> An initial half-life of 1 to 4 hours is probably more meaningful than the beta terminal half-life of 6 to 10 hours in view of the low serum concentration associated with the longer half-life (Daneshmend and Warnock et al, 1988)

■ **INDICATIONS**

ANTANAZOL Cream is indicated for the treatment of the following: Cutaneous candidiasis, Tinea corporis, Tinea cruris and Tinea (Pityriasis) versicolor, Seborrheic dermatitis.

■ **DOSAGE AND ADMINISTRATION**

Apply adequate amount one or two times daily to the affected area for 2 to 4 weeks. After clinical improvement occurs, treatment should be continued for several days.
Diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment

■ **CONTRAINDICATION**

Known hypersensitivity to ketoconazole and this product is not for ophthalmic use.

■ **PRECAUTIONS/WARNINGS**

1. Precaution before administration
   1) Do not apply to the eyes.
   2) Since allergy may be caused by propylene glycol which is contained as an additive in this drug, patients who have had hypersensitivity or history of allergy should consult with the physician or pharmacist before use
   3) Any topical steroid therapy should be reduced gradually when starting on topical ketoconazole cream to avoid skin irritation
2. Adverse reactions
   Rarely dermal irritation, dermatitis and burning sense may occur.

■ **DRUG INTERACTION**

None reported so far

■ **OVERDOSAGE**

Excessive topical application may lead to erythema, oedema and burning sensation which will disappear upon discontinuation of the treatment.

■ **STORAGE**

Store in a tight and light-resistant container at room temperature below 30℃

■ **HOW SUPPLIED**

10 g/Tube

■ **SHELF LIFE :** 3 years from manufacturing date.
For further information, please consult your doctor/pharmacist.

■ **Product Registration Holder:**

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