



CANDAZOLE CREAM 1% w/w

NAME AND STRENGTH OF ACTIVE SUBSTANCE : Clotrimazole 1% w/w (Micronised).

PRODUCT DESCRIPTION : A white cream.

Other ingredients: Xanthan Gum, Benzyl Alcohol, Polysorbate 60, Isopropyl Myristate, Sorbitan Monostearate, Cetyl Palmitate, Cetostearyl Alcohol and Purified Water.

PHARMACODYNAMICS : Clotrimazole is a broad spectrum imidazole anti-fungal agent.

It permeates the chitin of the fungal cell wall and increases the membrane permeability to various intracellular substances. Most strains of dermatophytes and Candida species are inhibited by concentrations of less than 2 mcg/ml.

PHARMACOKINETICS : When applied topically, clotrimazole penetrates the epidermis. Absorption of clotrimazole is less than 0.5% after application to the intact skin. The small amount absorbed is metabolized in the liver to inactive compounds and excreted in the bile and urine.

INDICATIONS : Topical treatment of tinea pedis, tinea cruris, tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, and Microsporum canis; tinea versicolor due to Malassezia furfur; erythrasma; candidiasis due to Candida albicans including cutaneous candidiasis, paronychia, external genital candidiasis and candidal balanitis.

CONTRAINDICATIONS : Hypersensitivity to clotrimazole, or any component in the preparation.

ADVERSE EFFECTS : In a small fraction of recipients, clotrimazole when applied topically may cause stinging, erythema, oedema, vesiculation, desquamation, pruritus and urticaria.

DRUG INTERACTION : Unknown.

WARNINGS AND PRECAUTIONS : If irritation or sensitivity occurs, treatment should be discontinued. Do not use on children under 2 years of age except under the advice and supervision of a doctor. Avoid contact with eyes and mucous membranes (for external use only). Consult doctor if no improvement is seen in 4 weeks (for athlete's foot) or 2 weeks (for jock itch).

PREGNANCY AND LACTATION : In the first trimester of pregnancy, clotrimazole should only be used when considered essential to the welfare of the patient. It is not known whether clotrimazole is excreted in breast milk or whether it has a harmful effect on the newborn.

RECOMMENDED DOSAGE : Wash and dry affected areas. Apply sparingly to the affected parts and surrounding skin areas twice daily, morning and evening. Regular applications are essential for successful treatment. Treatment should be continued for two weeks after all clinical signs have disappeared. Attention to hygiene is important in the management of fungal diseases, particularly of the folds and the feet. If no improvement is seen after 4 weeks, diagnosis should be reviewed.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S) : After topical application to the skin, clotrimazole penetrates the epidermis and deeper layers of the skin but less than 0.5% of the dose is absorbed systemically. No information is available concerning overdosage in human beings following topical application.

PACKING : Candazole Cream is packed in 15g tubes and 450g jars (for export only).

STORAGE : Keep containers well closed. Protect from light. Store below 30°C.

For external use only. Keep out of reach of children.

Recommended shelf-life : 3 years.

MANUFACTURED BY:

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