



CANDAZOLE LOTION 1% W/V

NAME AND STRENGTH OF ACTIVE SUBSTANCE : Clotrimazole 1% w/v.

PRODUCT DESCRIPTION : A Clear colourless lotion.

Other ingredients: Propylene Glycol.

PHARMACODYNAMICS : Clotrimazole is a broad-spectrum imidazole with potent anti-fungal against dermatophytes, including Epidermophytes, Microsporum, Trichophyton spp. and Malassezia furfur and Candida species.

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 2mcg/ml.

PHARMACOKINETICS : Clotrimazole is effective against a variety of fungi including Epidermophytes, yeasts, Microsporum, Trichophyton spp., and Malassezia furfur. When applied topically, clotrimazole penetrates the epidermis. Actinomycetes, gram-positive bacteria, certain anaerobes (such as Bacteroides fragilis) and Trichomonas vaginalis are also inhibited. 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 fungal treatment of tinea corporis, tinea cruris, tinea pedis, tinea versicolor and cutaneous candidiasis.

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, vesication, 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). Advise to consult doctor if no improvement is seen in 4 weeks (for athlete's foot) or 2 weeks (for jock itch). Not for ophthalmic use.

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 in the newborn.

ROUTE OF ADMINISTRATION : Topical.

RECOMMENDED DOSAGE : Wash and dry affected area. Apply sparingly to the affected parts and surrounding skin areas and rub in twice daily, morning and evening. Regular application is essential for successful treatment. Treatment should be continued for 2 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 after four 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 Lotion is packed in 10ml plastic dropper bottles.

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

Keep out of reach of children.

Recommended shelf-life: 2 years.

MANUFACTURED BY :

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