HOE
Est. 1979

DECOZOL CREAM

NAME AND STRENGTH OF ACTIVE SUBSTANCE : Miconazole Nitrate 2% w/w.
PRODUCT DESCRIPTION : White cream.
Other ingredients are Chlorocresol, Cetostearyl Alcohol, Macrogol Cetostearyl Ether (Cetomacrogol 1000), White Soft Paraffin, Liquid Paraffin, Propylene Glycol and Purified water.
PHARMACODYNAMICS : Miconazole is an imidazole antifungal agent which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi.
PHARMACOKINETICS : Miconazole has shown fungistatic activity, in vitro, against a number of fungi causing systemic mycoses such as *Coccidioides immitis, Histoplasma capsulatum, Blastomyces dermatitides* and *Cryptococcus neoformans.* Miconazole appears to act on the fungal cell wall and membranes inducing permeability changes which alter the ionic macromolecular composition of the effected cells. At high concentrations, Miconazole has shown fungicidal activity against various organisms. Miconazole readily penetrates the stratum corneum into the blood. Absorption is no more than 1.3% from the vagina.
INDICATIONS : For treatment of Tinea pedis (athlete's foot), tinea cruris and tinea corporis caused by *Trichophyton rubrum, Trichophyton mentagrophytes* and *Epidermophyton floccosum,* in the treatment of cutaneous candidiasis (moniliasis) and in the treatment of tinea versicolor.
CONTRAINDICATIONS : It is contraindicated in individuals who are hypersensitive to any of the components.
INTERACTIONS : Miconazole administered systemically is known to inhibit CYP2C9 enzyme system. Due to the limited systemic availability after topical application, clinically relevant interactions occur very rarely. In patients on warfarin which is subjected to metabolism by CYP2C9, caution should be exercised and the anticoagulant effect should be monitored (see Warnings and Special Precautions).
ADVERSE EFFECTS : Adverse effects from topical application to the vagina include burning, itching or irritation in about 7% of recipients and infrequently pelvic cramps (0.2%), headache, hives or skin rash. Irritation, burning and maceration are rare after cutaneous application. Miconazole is considered safe for use during pregnancy, although vaginal use should be avoided during the first trimester.
WARNINGS AND SPECIAL 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 there is no improvement in 4 weeks (for athlete's foot) or 2 weeks (for jock itch). Prolonged use of Miconazole, like any topical antimicrobial agent, may give rise to overgrowth of non susceptible organisms. In patients on warfarin, caution should be exercised and the anticoagulant effect should be monitored (see Interactions).
Use in pregnancy : Safety for use in pregnancy has not been established. Since Miconazole nitrate is absorbed in small amounts following topical administration, the drug should be used in the first trimester of pregnancy only if in the judgement of the treating clinician such treatment is considered essential to the welfare of the patient and the expected benefits outweigh any potential risks.
Use during lactation : It is not known whether or not Miconazole nitrate is excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when Miconazole is administered to a nursing mother.
ROUTE OF ADMINISTRATION : Topical
RECOMMENDED DOSAGE : Skin infection : Apply once or twice daily for 2 – 5 weeks.
Nail infection : Apply once daily. Treatment should be continued at least one week after disappearance of all signs and symptoms.
SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S) :
Overdosage with Miconazole nitrate in humans has not been reported to date.
PACKING : 15g collapsible aluminium tubes. 450g in polyethylene jars (for export only). Not all presentations may be available locally.
STORAGE : Keep container well closed. Protect from strong light. Store below 30°C. For external use only. Keep out of reach of children.
Recommended shelf-life : 3 years.
MANUFACTURED BY : HOE Pharmaceuticals Sdn. Bhd.
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