

APPROVED NAME: MICONAZOLE/HYDROCORTISONE CREAM

TRADE NAME: MICORT

REGISTRATION NUMBER

TBA

PHARMACOLOGICAL CLASSIFICATION: Imidazole and triazole derivatives, combinations : D01AC20

CATEGORY OF DISTRIBUTION:

Prescription Preparation - POM

DESCRIPTION: Micort Topical Cream is a smooth white cream

COMPOSITION:

Each gram of cream contains:

Miconazole Nitrate 20 mg

Hydrocortisone 10 mg

Preserved with chlorocresol 0.1 % m/m

PHARMACOLOGY:

Miconazole Nitrate is a synthetic 1-phenethylimidazole with a broad spectrum antifungal activity against dermatophytes, yeasts and other phycomycetes and adelomycetes and has a potent antibacterial activity against gram - positive bacilli and cocci. Miconazole inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane leading to fungal cell necrosis. Hydrocortisone is a natural corticosteroid with a potent anti-inflammatory and antipruriginous action. Miconazole is not significantly absorbed after topical application. Depending on the location and type of infection, hydrocortisone penetrates well into the skin and is partially absorbed. Metabolism occurs in the liver and tissues and excretion is through the urine mostly as glucuronides.

INDICATIONS:

Micort cream is indicated for:

- Infections of the skin by dermatophytes or candida spp in which inflammatory symptoms are prominent.
- Mycotic infections with bacterial superinfection.

CONTRAINDICATIONS:

Micort cream is not indicated in tuberculous skin infections, herpes simplex, vaccinia and all forms of varicella.

SIDE EFFECTS

Although local treatment is well tolerated, irritation and sensitivity may occur.

WARNINGS AND PRECAUTIONS

Caution is advised with pregnant women and infants if the medication is to be applied extensively or under occlusive dressing.

If a reaction suggesting sensitivity or irritation occurs, the treatment should be discontinued. Avoid introduction to the eyes.

DOSAGE AND ADMINISTRATION

Apply sparingly to the affected areas and rub in gently with fingers until the cream has been completely absorbed by the skin. Apply once or twice daily. Treatment with Micort cream (or subsequently with miconazole cream) should be continued uninterrupted until the lesion has completely disappeared (usually 2 - 5 weeks)

OVERDOSAGE AND ITS TREATMENT:

Prolonged and excessive use can lead to skin irritation which usually disappears upon discontinuation of therapy. Topically applied, corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

If accidental ingestion of large quantities of Micort occurs, an appropriate method of gastric emptying may be used.

PRESENTATION:

In tubes of 15 g.

SHELF LIFE

24 months

STORAGE:

Store below 25 °C away from light. Keep out of reach of children.

MANUFACTURER AND MARKETING AUTHORISATION HOLDER

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HARARE

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