

<b>MINACORT CREAM</b>
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**NAME AND STRENGTH OF ACTIVE SUBSTANCE(S) :**

Each gram contains:

Miconazole Nitrate..... 20mg

Hydrocortisone Acetate.....10mg

**PRODUCT DESCRIPTION:**

A white to off-white cream base with whitening bouquet fragrance in printed aluminium tubes with white caps.

**PHARMACODYNAMICS:**

Miconazole is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It inhibit several genera of fungi, including dermatophytes and yeasts, and gram +ve bacteria.

Hydrocortisone produces dramatic suppression of skin disease, such as eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, seborrhoeic dermatitis, neurodermatitis, some forms of psoriasis and intertrigo, in which inflammation is a prominent feature. Miconazole in combination with hydrocortisone acts very rapidly on pruritus, which frequently accompanies dermatophyte and yeast infections.

**PHARMACOKINETICS:**

There is little absorption through skin or mucous membrane when Miconazole is applied topically. Miconazole readily penetrates the stratum corneum of the skin and persists there for more than 4 days after application, which probably contributes to its efficacy against the dermatophytes. From topical sites, only trace amount of Miconazole appeared in blood or urine. Hydrocortisone Acetate is absorbed through the skin, particularly in denuded area. It is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone. The biological half-life is about 100 minutes. More than 90% bound to plasma proteins.

**INDICATION:**

Topical treatment of fungal infections associated with inflammatory symptoms. It may also be used for mycotic affections with bacterial superinfection.

**RECOMMENDED DOSAGE:**

Apply thinly once or twice daily. It should be rubbed in gently with finger until completely penetrated into the skin. Long term continuous topical corticosteroid therapy should be avoided in infants. Corticosteroids should be used sparingly and for short periods of time in elderly due to natural skin thinning.

**ROUTE OF ADMINISTRATION:**

Topical route

**CONTRAINDICATIONS:**

Hypersensitivity to Miconazole, Hydrocortisone or other ingredient in the cream. Tuberculous skin infections, herpes simplex, vaccinia and all forms of varicella. It is not indicated for infections caused by gram negative bacteria.

**WARNINGS AND PRECAUTIONS:**

- i) Avoid contact with the eyes.
- ii) If irritation occurs, or no improvement is seen within 4 weeks, discontinue treatment and patient should consult a physician or pharmacist.
- iii) Care is advised if use in infants and children when cream is to be applied to extensive surface areas or under occlusive dressings including baby napkins. Similarly application to the face should be avoided.
- iv) Long term continuous topical corticosteroid therapy should be avoided in infants. Adrenal suppression can occur even without occlusion.
- v) In patients on warfarin, caution should be exercised and the anticoagulant effect should be monitored (see Interactions).

**INTERACTION WITH OTHER MEDICAMENTS:**

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 Precautions).

**PREGNANCY AND LACTATION:**

Should be used cautiously during pregnancy and lactation period. Avoid treatment of large surfaces and application under occlusive dressing.

**ADVERSE EFFECTS:**

Irritation or burning sensation have been reported. Allergic reaction to any of the ingredient of the cream may occur.

**SYMPTOMS AND TREATMENT OVERDOSE:**

Overdose after prolonged and excessive use can result in skin irritation, which usually disappear after discontinuation of therapy. Topically applied corticosteroid can be absorbed in sufficient amounts to produce systemic effects.

If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered to be necessary.

**EFFECT ON ABILITY TO DRIVE AND USE MACHINE**

No influence on the ability to drive and use machines.

**PRECLINICAL SAFETY DATA**

Not applicable.

**INSTRUCTION FOR USE**

To be used topically, to the affected skin areas.

**STORAGE CONDITIONS:**

Store below 30°C in well-closed containers. Protect from light, heat, moisture and freezing. Keep medicine out of the reach of children / Jauhi dari kanak-kanak.

**DOSAGE FORMS AND PACKAGING AVAILABLE:**

Dosage Form: Cream

Packing size: 15g (aluminium tube), 50x15g.

**NAME AND ADDRESS OF MANUFACTURER /PRODUCT REGISTRATION HOLDER:**

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas,  
Pulau Pinang, Malaysia.

**DATE OF REVISION:**

09/10/2022