

MECANDIN CREAM 2% W/W

NAME AND STRENGTH OF ACTIVE SUBSTANCE :

Each gram contains:

Miconazole Nitrate..... 20mg

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.

Miconazole is fungistatic or may be fungicidal, depending on concentration. It inhibits biosynthesis of ergosterol or other sterols, damaging the fungal cell wall membrane and altering its permeability, as a result, loss of essential intracellular elements may occur. Miconazole also inhibits biosynthesis of triglycerides and phospholipids by fungi; in addition, inhibits oxidative and peroxidative enzyme activity, resulting in intracellular buildup of toxic concentrations of hydrogen peroxide which may contribute to deterioration of subcellular organelles and cellular necrosis. In *Candida albicans*, it inhibits transformation of blastospores into invasive mycelial form.

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.

INDICATION:

Treatment of fungal infections of skin and nails including cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis and tinea versicolor (pityriasis versicolor).

RECOMMENDED DOSAGE:

Apply some cream to the lesions twice a day. Rub the cream with your finger into the skin until it has fully penetrated. Treatment should be continued at least one week after disappearance of all signs and symptoms.

ROUTE OF ADMINISTRATION:

Topical route

CONTRAINDICATIONS:

Contra-indicated in patient with known hypersensitivity to the drug.

WARNINGS AND PRECAUTIONS:

- i) In patients on warfarin, caution should be exercised and the anticoagulant effect should be monitored (see Interactions).
- ii) Avoid contact with the eyes.
- iii) If irritation occurs, or no improvement is seen within 4 weeks, discontinue treatment and patient should consult a physician or pharmacist.
- iv) *Pediatric Precautions* : Topical Miconazole Nitrate preparations should be used in children younger than 2 years of age under the direction and supervision of a physician. Use of the topical preparations in children 2-11 years of age should be supervised by an adult.
- v) Not applying occlusive dressing over this medication unless directed to do so by physician.

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:

Problems in humans have not been documented, even though small amounts of topical Miconazole are absorbed systemically.

ADVERSE EFFECTS:

Local irritation and sensitivity reactions may occur when Miconazole Nitrate is used topically; contact dermatitis has been reported.

SYMPTOMS AND TREATMENT OVERDOSE:

Excessive use can result in skin irritation which usually disappears after discontinuation of therapy. In the event of accidental ingestion, an appropriate method of gastric emptying may be used if considered appropriate.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE

Not applicable.

PRECLINICAL SAFETY DATA

Not applicable.

INSTRUCTION FOR USE

To be used topically, to the affected skin areas.

STORAGE CONDITIONS:

Store below 30⁰C 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:

24/11/2021