

<b>CANEZIN CREAM 1%W/W</b>
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**NAME AND STRENGTH OF ACTIVE SUBSTANCE :**

Each gram contains:

Clotrimazole ..... 10mg

**PRODUCT DESCRIPTION:**

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

**PHARMACODYNAMICS:**

Clotrimazole is an imidazole antifungal agent that may act on the cell membrane of the fungus. It is fungistatic and 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. It 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 that may contribute to deterioration of subcellular organelles and cellular necrosis. In *Candida albicans*, inhibits transformation of blastospores into invasive mycelia form.

**PHARMACOKINETICS:**

Systemic absorption of Clotrimazole is less than 0.5% after application to the intact skin. The small amount absorbed is metabolized in the liver and excreted in bile, following application to the skin, highest concentrations of clotrimazole are present in the stratum corneum; lower drug concentrations occur in the stratum spinosum and the papillary and reticular dermis.

**INDICATION:**

It is indicated for the treatment of:

1. All dermatomycoses due to dermatophytes (e.g. *Trichophyton* species).
2. All dermatomycoses due to yeast (*Candida* species).
3. Dermatomycoses due to moulds and other fungi.
4. Skin diseases showing secondary infection with these fungi.

The dermatomycoses listed under 1-4 belong to for example:- interdigital mycoses (e.g. athlete's foot), paronychias (associated with nail mycoses), mycoses in skin folds, candida vulvitis, candida balanitis, pityriasis versicolor, and erythrasma.

**RECOMMENDED DOSAGE:**

Clotrimazole cream is applied topically two or three times daily for 2 to 4 weeks as a 1% cream.

**ROUTE OF ADMINISTRATION:**

Topical

**CONTRAINDICATIONS:**

Clotrimazole is contraindicated in patients who are hypersensitive to the drug or any ingredient in the formulation.

**WARNINGS AND PRECAUTIONS:****Precautions while using this medication**

Clinical improvement and relief of pruritus usually occur within 1 week; however up to 8 weeks of therapy may be required for mycological cures, especially in the treatment of tinea pedis. If clinical improvement does not occur after 4 weeks of treatment, the diagnosis should be reevaluated.

**INTERACTION WITH OTHER MEDICAMENTS:**

None known

**STATEMENT ON USAGE DURING PREGNANCY AND LACTATION:**

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

**ADVERSE EFFECTS/UNDESIRABLE EFFECTS:**

Although Clotrimazole is usually well tolerated when administered topically to the skin, the following side effects/adverse reactions may occasionally occur:

Skin rash, hives, blistering, burning, itching, peeling, redness, and stinging, swelling, or other sign of skin irritation not present before therapy.

**SYMPTOMS AND TREATMENT OVERDOSE:**

In the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of Clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

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

Clotrimazole cream has no or negligible influence on the ability to drive or 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 the medicine out of 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:**

01/12/2021