**Dazole® Cream**
**(Clotrimazole Cream)**

**Description:** A white non-greasy, non- gritty Cream.

**Composition**:

Contains Clotrimazole 1% w/w.

**Pharmacology**

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc. Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate.The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides). Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

**Pharmacokinetics.**

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

**Indications:**

For the treatment of:

i. All dermatomycoses due to moulds and other fungi (e.g. *Trichophyton* species)

ii. All dermatomycoses due to yeasts (*Candida* species). These include ringworm (tinea) infections (e.g. athlete's foot), paronychia, pityriasis versicolor, erythrasma and intertrigo.

iii. Skin diseases showing secondary infection with these fungi.

iv. Candidal nappy rash, vulvitis and balanitis.

**Dosage**

***Posology:*** There is no separate dosage schedule for the young or elderly and for external use only.

***Method of administration***: The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently. Clotrimazole is applied topically two or three times daily for 2 to 4 weeks as a 1% cream in the treatment of fungal skin infections; A strip of cream (½ cm long) is enough to treat an area of about the size of the hand. If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream. Treatment should be continued for at least one month for dermatophyte infections, or for at least two weeks for candidal infections.

**Contra-indications**

Hypersensitivity to the active substance or to any of the excipients and do not use the cream to treat nail or scalp infections.

**Special warnings and precautions for use**

Contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

**Interaction with other medicinal products and other forms of interaction**

Dazole cream may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

**Fertility, pregnancy and lactation**

At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy but only under the supervision of a physician or midwife. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. Animal studies have not demonstrated any effects of the drug on fertility.

**Effects on ability to drive and use machines**: Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

**Undesirable effects**: Undesirable effects are based on spontaneous reports. The most side effects includes Immune system disorders: allergic reaction (syncope, hypotension, dyspnoea, and urticaria).Skin and subcutaneous tissue disorders includes blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, and rash, stinging and burning.

**Overdose**: No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

**Distribution Category:** POM

**Presentation:** Collapsible aluminium tubes of 20 gm.

**Shelf-life:** Three years after the date of manufacture.

**Storage:** Store below 30ºC in a cool dry place. Protected from direct sunlight. Keep out of reach of children.

**Manufactured By:**

**DAWA Limited,**
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**P. O. Box 16633 – 00620, Nairobi, Kenya.**

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