

SM PHARMACEUTICALS SDN. BHD.

CLOZOLE CREAM
(*CLOTRIMAZOLE CREAM 1%*)

DESCRIPTION:

A smooth, soft, homogenous cream, white in colour and has slightly waxy odour.

COMPOSITION:

Each 1 g cream contains:

Clotrimazole 10 mg.

Methyl Paraben 0.25 mg and Propyl Paraben 0.15 mg as preservatives.

ACTIONS AND MODE OR MECHANISMS OF ACTION:

Fungistatic; may be fungicidal, depending on concentration; 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; also inhibits biosynthesis of triglycerides and phospholipids by fungi; in addition, inhibits oxidative and peroxidative enzyme activity, resulting in intracellular buildup of toxic concentration of hydrogen peroxide which may contribute to deterioration of subcellular organelles and cellular necrosis.

In *Candida albicans*, inhibits transformation of blastospores into invasive mycelial form.

PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS):

Absorption: Dermal penetration; minimal systemic absorption.

INDICATIONS:

Candidiasis, cutaneous (treatment) - Cutaneous candidiasis caused by *Candida albicans*. Tinea corporis, Tinea cruris, Tinea pedis, Tinea versicolor.

CONTRAINDICATIONS:

Contraindicated in patients who are hypersensitivity to clotrimazole and propylene glycol.

SIDE EFFECTS / ADVERSE REACTIONS:

Local reaction including irritation and mild burning. Contact allergic dermatitis.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:

Usual adult dose: Topical, to the skin, two times a day, morning and evening.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTES:

Use of topical antifungals may lead to skin sensitisation, resulting in hypersensitivity with subsequent topical use of the medication.

Improvement of condition, with relief of pruritus, usually occurs within first week of therapy. When this medication is used in the treatment of candidiasis, occlusive dressings should be avoided since they provide conditions, which favour growth of yeast and release of its irritating endotoxin. In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed as soon as possible after ingestion.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:

Store below 30°C. Protect from light and freezing.

Keep out of reach of children

Continue medicine for full time of treatment.

Avoiding contact with the eyes

Use in pregnancy:

Clotrimazole should be used in pregnancy only when considered necessary by the clinician.

PACKING / PACK SIZES:

Aluminium collapsible tubes of 15 g.

SHELF LIFE: 3 years

MANUFACTURER AND PRODUCT REGISTRATION HOLDER:

SM PHARMACEUTICALS SDN BHD (218620-M)

Lot 88, Sungai Petani Industrial Estate

08000 Sungai Petani

Kedah Darul Aman, Malaysia.

06.06.2017