1. NAME OF THE MEDICINAL PRODUCT

KEMI CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

15gm cream contains:
Clotrimazole 1%
Beclomethasone Dipropionate 0.025%

3. PHARMACEUTICAL FORM

Topical dosage form.

A white semi-solid cream filled in 15 gm collapsible white tube

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Kemi Cream is indicated for fungal infections of skin including Tinea Capitis, Tinea Faciei, Tinea Corporis, Tinea pedis, Candidal intertrigo.Tinea versicolour.

It also useful for dermatitis, otitis externia.

4.2 Posology and method of administration

Kemi cream is applied topically. Wash affected areas well, rinse off all traces of soap, dry, and apply sparingly twice daily.

4.3 Contraindications:

Since KEMI contains a steroid, Beclomethasone Dipropionate, the risk of systemic absorption should be considered when applying the cream. Kemi Ointment should not be applied with an occlusive dressing to large areas of the body. It should not be used indiscriminately for pruritis. It should not be applied to ulcers of the leg and long term topical use is best avoided, especially in children.

4.4 Special warnings and precautions for use:

For topical use only. Avoid contact with eyes, lips or mucous membranes.

This medication is to be used as directed by a physician and should not be used totreat any condition other than that for which it was prescribed. If redness or irritation occurs, discontinue use and consult a physician.

4.5 Pregnancy and lactation

No report exists on the topical use to establish any adverse effect to pregnant or nursing mothers

4.6 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.7 Undesirable effects

The following adverse reactions have been reported with the use of Clotrimazole: Erythema, Stinging, Blistering, Oedema, Pruritus, Burning and general irritation to the skin. Corticosteroids have antiproliferative effects on keratinocytes and fibroblasts (leading to skin thinning and atrophy. Shin thinning is more likely if corticosteroid preparations are applied under occlusion.

4.8 Overdose

Excessive use of Kemi cream may result in the following because of the corticosteroid content, thinning of the skin which may be restored over a period of time increased hair growth, acne at the site of application in some cases. Discontinuation of use can restore the damage after a period of time has elapsed.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action of Clotrimazole

Clotrimazole is an imidazole antifungal agent. Imidazoles inhibit 14-α-demethylation of lanosterol in fungi by binding to one of the cytochrome P-450 enzymes. This leads to the accumulation of 14-α-methylsterols and reduced concentrations of ergosterol, a sterol essential for a normal fungal cytoplasmic membrane. The methylsterols may affect the electron transport system, thereby inhibiting growth of fungi.

Clotrimazole is fungicidal or fungistatic depending on the drug concentrations. It inhibits the conversion of Lanosterol to 14 demethylLanosterol by inhibiting the cytochromeP450 enzyme 14 alpha demethylase and impair ergosterol synthesis which is an essential constituent of cell membrane. Inhibition of ergosterol synthesis will alter the membrane permeability of the susceptible fungus and kill or inhibit them.

Mechanism of Action of Beclomethasone dipropionate

Mechanism of action: The drug exerts its pharmacological action by penetrating and binding to cytoplasmic receptor protein and causes a structural change in steroid receptor complex. This structural change allows it`s migration in to the nucleus and then binding to specific sites on the DNA which leads to transcription of specific m-RNA and which ultimately regulates protein synthesis. It exerts highly selective glucocorticoid action. It stimulates the enzymes needed to decrease the inflammatory response.The drug exerts anti-inflammatory and immunosuppressant actions as follows: -

1) Induce lipocortins in macrophages, endothelium, and fibroblasts which inhibits Phospholipase A2 and thus decreases the production of Prostaglandins, leukotrienes (LT), and platelet activating factor,

2) Causes negative regulation of genes for cytokines in macrophages, endothelial cells and lymphocytes and thus decreases the production of interleukins (IL-1, IL-2, IL-3, IL-6), TNF-alpha, GM-CSF (granulocyte macrophage colony stimulating factor), Gama interferon and suppresses fibroblast proliferation and T-lymphocyte functions and interferes chemo taxis.

3) Decreases the production of acute phase reactants from macrophages and endothelial cells and interferes complement function.

4) Decreases the production of ELAM-1(Endothelial leukocyte adhesion molecule-1) and ICAM-1(intracellular adhesion molecule-1) in endothelial cells.

5) Inhibit IgE mediated histamine and LT-C4 release from basophiles and the effects of antigen-antibody reaction is not mediated 6) Reduces the production of collagenase and stromolysin and thus prevents tissue destruction.

5.2 Pharmacokinetic properties

Absorption: Absorption is minimal after topical administration.

Pharmacokinetics of Beclomethasone dipropionate

Absorption: It enters in to the systemic circulation after topical administration.
The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption of topical corticosteroids. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, the pharmacokinetics of topical corticosteroids is similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying

degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

Studies performed with Clotrimazole and Betamethasone Dipropionate Cream indicates that these topical combination anti-fungal/corticosteroids may have vasoconstrictor potencies in a range that is comparable to high potency topical corticosteroids. Therefore use is not recommended in patients less than 17 years of age, in diaper dermatitis, and under occlusion.

5.3 Preclinical safety data

Long-term animal studies for carcinogenic potential have not been performed on thisproduct to date. Studies on reproduction and fertility also have not been performed.

6 Pharmaceutical particulars

6.1 List of excipients

Cetomacrogol 1000 BP

Cetostearyl Alcohol BP

Propylene Glycol

Liquid Paraffin

Methyl Paraben

Propyl Paraben

Purified Water BP

6.2Incompatibilities

None

6.3Shelf life

3 years

6.4 Special precautions for storage

Preserve in tight containers. Protect from light.
Store at temperature below 30°C

6.5 Nature and contents of container

15gm white collapsible tube

7.0 MARKETING AUTHORISATION HOLDERJAWA

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