1.0 Name of the Finished Pharmaceutical Product

KOKOBACT CREAM [Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream]

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each gm Contains:

Betamethasone Dipropionate USP

Eq. to Betamethasone 0.05%w/w

Neomycin Sulfate USP

Eq.to Neomycin 0.5%w/w

Clotrimazole USP 1.0%w/w

Cream Base q.s

3.0 Pharmaceutical Dosage Form

Topical Use only

White colour, semisolid cream, filled in white coloured lami tube.

4.0 Clinical Particulars

Therapeutic Indications

Antifungal, Anti-inflammatory, Antibacterial

Betamethasone Dipropionate is a very active topical corticosteroid which is of particular value when used in short courses for the treatment of more resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid lupus erythematosus, and other skin conditions which do not respond satisfactorily to less active steroids.

Clotrimazole an imidazole-piperazine compound, is an orally active antimycotic agent. In addition, clotrimazole is a specific inhibitor of cytochrome P450 3A4.

Neomycin is an aminoglycoside class of antibiotics that contain two or more amino sugars connected by glycosidic bonds. Neomycin Sulphate is used to prevent and treat bacterial infections of the skin.

Posology and Method of Administration

-Oral ******NO

-Intravenous* ***NO

-Intramuscular* ***NO

-Topical* ********√* **YES

-Inhalation* *****NO

Contraindications

Hypersensitivity to the active substance or any of the excipients.

The following conditions should not be treated with Nortex Cream:

• Untreated cutaneous infections

• Rosacea

• Acne vulgaris

• Pruritus without inflammation

• Perianal and genital pruritus

• Perioral dermatitis.

Betamethasone is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions.

Special Warning And Precautions For Use

KOKOBACT CREAM [Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole] is not for ophthalmic use.

Suitable precautions should be taken if extensive body surface areas are treated, occlusive technique is used, or when long term use is anticipated, particularly in infants and children.

Prolonged use of topical antibiotics may result in overgrowth of non-susceptible organisms, irritation, sensitization or super infection develops, if this occurs, treatment with **KOKOBACT CREAM** [Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole] should be discontinued and appropriate therapy instituted.

Interaction with Other Medicinal Products and Other Forms of Interaction

Pregnancy: Teratogenic Effects: Pregnancy Category C: Although there is no evidence of risk to the foetus, caution is advised during pregnancy and lactation.

Fertility, pregnancy and lactation

Betamethasone Dipropionate

There are limited data from the use of betametha sone Diprop ionate in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal Development.

The relevance of this finding to humans has not been established. Administration of this cream during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of clobetasol during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation clobetasol should not be applied to the breasts to avoid accidental ingestion by the infant.

There are no data in humans to evaluate the effect of topical corticosteroids on fertility

Clobetasol administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose.

Neomycin Sulfate:

The manufacturer makes no recommendation regarding use during pregnancy and lactation for Neomycin Sulfate. US FDA pregnancy category: Not formally assigned to a pregnancy category.

Animal studies have not been reported. There are no controlled data in human pregnancy.

Clotrimazole:

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical clotrimazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of clotrimazole

Effects on Ability to Drive and Use Machines

The medicinal product has no influence on the ability to drive or operate machinery

Undesirable Effects

Common side effects include skin conditions like itching, burning, stinging, dryness, scaly patches and redness.

Seek medical attention if any adverse effects occur.

For a comprehensive list of all possible effects, consult your doctor.

If any symptom persists or gets worse, or you notice any other symptom, then please call your doctor immediately.

Overdose

Antifungal, Anti-inflammatory, Antibacterial

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Clotrimazole, an imidazole-piperazine compound, is an orally active antimycotic agent. In addition, clotrimazole is a specific inhibitor of cytochrome P4503A4.

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5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacodynamics

Betamethasone Dipropionate is topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Neomycin Sulfate actively transported across the bacterial cell membrane, binds to a specific receptor protein on the 30 S subunit of bacterial ribosomes, and interferes with an initiation complex between mRNA (messenger RNA) and the 30 S subunit, inhibiting protein synthesis. DNA may be misread, thus producing non-functional proteins; polyribosomes are split apart and are unable to synthesize protein.

In vitro studies suggest that clotrimazole impairs the synthesis of ergosterol, which is a vital component of fungal cell membranes. It is postulated that the therapeutic effect of clotrimazole in seborrheic dermatitis is due to the reduction of M. ovale, but this has not yet been proven.

5.2 Pharmacokinetic Properties

Clotrimazole: When cream was applied dermally to intact or abraded skin of beagle dogs for 28 consecutive days at a dose of 80 mg, there were no detectable plasma levels using an assay method having a lower detection limit of 2 ng/mL. After a single topical application to the chest, back and arms of normal volunteers, systemic absorption of clotrimazole was not detected at the 5 ng/mL level in blood over a 72-hour period. Two dermal irritancy studies, a human sensitization test, a phototoxicity study and a photo allergy study conducted in 38 male and 62 female volunteers showed no contact sensitization of the delayed hypersensitivity type, no irritation, no phototoxicity and no photo allergenic potential due to cream.

Betamethasone Dipropionate: The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier.

Occlusive dressing with hydrocortisone for up to 24 hours has not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Neomycin Sulfate: Although not absorbed through intact skin, topical neomycin is readily absorbed from large denuded, burned, or granulating areas.

Preclinical Safety Data

Not Applicable

6.0 Pharmaceutical Particulars

List of Excipients

Disodium EDTA BP, Purified Water BP, Chlorocresol BP, Sodium Di Hydrogen Ortho Phosphate BP, Methyl Paraben Sodium BP, Propyl Paraben Sodium BP, White petroleum Jelly BP, Propylene Glycol BP, Cetomacrogal 1000 BP, Glyceryl mono stearate BP, Ginol-EW (6820) BP, Light liquid Parafine BP

Incompatibilities

None

Shelf Life

36 Months

Special Precautions for Storage

Store at a temperature below 30°C. Do not freeze.

Keep medicine out of reach of children. Keep the tube tightly closed after use.

Nature and Contents of Container

30g LAMI Tube packed in a unit carton.

6.6 Instruction for use and Handling

Patients should be advised to wash their hands after applying cream unless it is the hands that are being treated. Avoid contact with eyes.

7.0 Marketing Authorization Holder and Manufacturing Site Addresses

ADMINISTRATIVE DATA:

7.1 Marketing authorisation holder

Kremoint Pharma Pvt. Ltd.,

B-8 Additional MIDC, Ambernath

Ambernath (E). Thane 421506

8. Marketing authorisation number(s):

MH/DRUGS/146

9. Date of first authorisation/renewal of the authorisation -

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10. Date of revision of the text: -

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