1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC):

1. NAME OF THE MEDICINAL PRODUCT: NEUTRODERM CREAM (Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each gm Contains:

Betamethasone Dipropionate USP.....…..……..0.643 mg
Gentamicin Sulfate BP
Equivalent to Gentamicin base……1 mg
Tolnaftate USP……10 mg
Iodochlorhydroxyquinoline…..……10 mg
Cream Base…….……..…Q.S.

3. PHARMACEUTICAL FORM: TOPICAL CREAM

A white to off-white smooth perfumed cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

NEUTRODERM CREAM (Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream) combines the anti-inflammatory and antipruritic agent (betamethasone), the wide spectrum antibiotic (gentamicin), the fungicidal agent (tolnaftate), the antiseptic and antipruritic agent (Iodochlorhydroxyquinoline).

NEUTRODERM CREAM (Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream) is indicated for the relief of the inflammatory manifestations of corticosteroid-responsive dermatosis when complicated by secondary infection caused by organisms sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected. Such disorders include Inguinal dermatosis and dermatophytosis, tinea pedis, tinea corporis, anal pruritus, balano-posthitis, intertrigo, angular-stomatitis, impetigo, follicular dermatitis, pustular acne, seborrheic dermatitis, eczema, contact dermatitis, photosensitivity dermatitis, eczematoid dermatitis, chronic dermatitis of the extremities, neurodermatitis, dyshidrosis and paronychia.

4.2 Posology and method of administration

Direction: Direction: A thin film of cream should be applied to cover completely the affected area 2 – 3 times daily.

Route: For external application only.

Dosage:

A thin film of cream should be applied to cover completely the affected area 2 – 3 times daily. Or as prescribed by the physician.

Frequency of application and duration of therapy should be determined according to severity of the condition and patient response.

In cases of tinea pedis, longer therapy (2 – 4 weeks) may be necessary.

4.3 Contraindications

NEUTRODERM CREAM (Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream) is Contraindicated to patients with tuberculous lesions of the skin, acute herpes simplex, vaccine or varicella. Avoid use in or near the eyes. The safety of use in pregnant females has not been absolutely established. Therefore, they should not be used extensively on pregnant patients, in large amounts or for prolonged period.

4.4 Special warnings and precautions

NEUTRODERM CREAM (Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream) 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 Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream should be discontinued, and appropriate therapy instituted.

Systemic absorption of Iodochlorhydroxyquinoline may interfere with thyroid function tests. Slight staining of linens or clothing due to Iodochlorhydroxyquinoline may occur.

4.5 Interaction with other medicinal products and other form of interactions:

No interaction have been reported on local application with Neutroderm Cream.

4.6 Fertility, Pregnancy and Lactation

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

4.7 Effects on Ability to Drive and Use Machines

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

4.8 Undesirable effects:

Local adverse reactions reported with the use of topical corticosteroids, especially under occlusive dressings, include: Burning, itching, irritation, dryness, folliculitis, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Rash, irritation and hypersensitivity may occur with the topical usage of gentamicin, Iodochlorhydroxyquinoline and rarely with tolnaftate.

4.9 Overdose

Signs and symptoms

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Mechanism of Action

NEUTRODERM CREAM (Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream) is a combination of the anti-inflammatory, antipruritic and vasoconstrictive agent betamethasone dipropionate, the wide-spectrum antibiotic gentamicin sulfate, the fungicidal agent tolnaftate and Iodochlorhydroxyquinoline an antibacterial and antifungal agent.

The exact mechanisms of actions of Betamethasone dipropionate in each disease are uncertain. Betamethasone dipropionate, a corticosteroid, has been shown to have topical (dermatologic) and systemic pharmacologic and metabolic effects characteristic of this class of drugs.

Aminoglycosides like gentamicin "irreversibly" bind to specific 30S-subunit proteins and 16S rRNA. Specifically, gentamicin binds to four nucleotides of 16S rRNA and a single amino acid of protein S12. This interferes with decoding site in the vicinity of nucleotide 1400 in 16S rRNA of 30S subunit. This region interacts with the wobble base in the anticodon of tRNA. This leads to interference with the initiation complex, misreading of mRNA so incorrect amino acids are inserted into the polypeptide leading to non-functional or toxic peptides and the breakup of polysomes into non-functional monosomes. Tolnaftate is a topical fungicide. Though its exact mechanism unknown, it is believed to prevent ergosterol biosynthesis by inhibiting squalene epoxidase. It has also been reported to distort the hyphae and to stunt mycelial growth in susceptible organisms.

Iodochlorhydroxyquinoline has broad-spectrum antibacterial with antifungal properties. It is bacteriostatic; however, the precise mechanism of its action is unknown.

5.2 Pharmacokinetic properties:

Betamethasone (as Dipropionate): Betamethasone when applied topically, particularly under an occlusive dressing when the skin is broken, enough corticosteroids may be absorbed to give systemic effects. It is metabolized in the liver and distributed throughout body tissues; crosses the placenta and enters the breast milk. Excretion is via urine.

Gentamicin (as sulfate): Systemic absorption of gentamicin have been reported after topical use on denuded skin and burns.

Tolnaftate: The absorption after topical application is negligible.

Iodochlorhydroxyquinoline: Topical absorption is rapid and extensive, especially when the skin is covered with an occlusive dressing or if the medication is applied to extensive or eroded areas of the skin. Iodochlorhydroxyquinoline is absorbed through the skin in sufficient amounts to affect thyroid function tests.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Cetomacrogol 1000

Cetostearyl Alcohol

White Soft Paraffin

Chlorocresol

Propylene Glycol

Disodium Hydrogen Phosphate Perfume

Zigmond K00321/A

Purified Water

6.2 Incompatibilities

Not known

6.3 Shelf Life

36 months

6.4 Special precaution for storage

Store at a temperature not exceeding 30°C., Protect from light, do not refrigerated. Keep out of the reach of children.

6.5 Nature and content of container

The cream is filled into lami tubes with white colour stand-up caps and enclosed in an outer carton. Pack sizes available are 30g.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

Kremoint Pharma Pvt. Ltd.,

B-8 Additional MIDC, Ambernath

Ambernath (E). Thane 421506,

Maharashtra, India.

8. MARKETING AUTHORISATION NUMBER(S)

28-KD/146

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT
