NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

Product Name

MC FORIS CLOTRIMAZOLE, BETAMETHASONE AND NEOMYCIN CREAM

(Clotrimazole, Betamethasone and Neomycin Cream)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the Medicinal Product

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2. Qualitative and Quantitative Composition

Composition

Clotrimazole USP 1.0 % w/w

Betamethasone Dipropionate USP

Eq. to Betamethasone 0.05% w/w

Neomycin Sulphate USP 0.5% w/w

Cream Base q.s.

3. Pharmaceutical Form

Cream

4. Clinical Particulars

4.1 Therapeutic indications

Clotrimazole, Betamethasone and Neomycin Cream is indicated for the relief of the inflammatory manifestatios of corticosteroid responsive dermatoses when complicated by secondary infection caused by organism sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected.

4.2 Posology and method of administration Dosage and Administration

A small quantity of Clotrimazole, Betamethasone and Neomycin cream should be applied to cover completely the affected area two or three times daily, or as prescribed by the physician. Frequency of application should be determined according to severity of the condition.

During the therapy should be determined by patient response. In cases of tinea pedis, longer therapy should be determined by patient response. Incases of tinea pedis, longer therapy (2-4 weeks) may be necessary.

4.3 Contraindications

Clotrimazole, Betamethasone and Neomycin Cream is contra-indicated in those patients with a history known sensitivity reactionsto to any of its components.

4.4 Special warning and special precaution for use

Betamethasone dipropionate has potent glucocorticosteroid and weak mineralocorticosteroid activity. The mechanism for anti-inflammatory activity of the topical steroids, is unclear. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leucotriens by inhibiting the release of their common precursor, arachidonic acid. Corticosteroids are also thought to act by the induction of phospholipase A2 inhibitory proteins.

Clotrimazole exerts antifungal effects by inhibition of fungal sterol synthesis. It appears to inhibit the enzymatic conversion of 2,4 methylenedihydrolanosterol to dimethylsterol, the precursor to ergosterol, which is an essential building block of the cytoplasmic membrane of the fungi.

Clotrimazole is a broad spectrum antifungal agent that inhibits the growth of most fungi pathogenic to man, including the candida and deramtophytes (Trichophyton, Microsporum, Epidermophyton).

Neomycin actsacts on the bacteria by interfering with bacterial protein synthesis by binding to 30 ribosomes. The antibacterial spectrum of neomycin includes specific organisms which are susceptible to it and generally includes all medically important aerobic gram-negative bacilli except Pseudomonas aeruginosa. Aerobic bacteria are resistant. Staphylococcus aureus and Staph. Epidermidis are higly sensitive, but all streptococci are relatively resistant.

4.5 Interaction with other medicinal products and form of interaction

Since systemic absorption of Clotrimazole from a topical application is very low such interactions are very unlikely. There are no known interactions with Clotrimazole but for a list of interactions known with oral Clotrimazole the data sheet for oral dosage forms should be consulted.

4.6 Pregnancy and lactation

Clotrimazole

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses.

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.

Lactation:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. 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.

4.7 Effects on ability to drive and use machines

Clotrimazole, Betamethasone and Neomycin Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions reported for Lotriderm include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.

Reactions to betamethasone dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae miliaria, capillary fragility (ecchymoses), blurred vision and sensitisation.

4.9 Overdose

SYMPTOMS: Excessive or prolonged use of topical corticosterois can suppress pituitary adrenal function, resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism including cushing disease.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vasoconstrictor Assay

Studies performed with clotrimazole and betamethasone dipropionate cream indicate that these topical combination antifungal/corticosteroids may have vasoconstrictor

potencies in a range that is comparable to high-potency topical corticosteroids. However, similar blanching scores do not necessarily imply therapeutic equivalence.

5.2 Pharmacokinetic properties

Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease process in the skin may increase percutaneous absorption. Systemic absorption following use of topical clotrimazole preparation is very low. Estimated bioavailability is less than 0.5 % clotrimazole concentrations achieved in the epidermal layers exceed the minimal inhibitory concentrations (MICs) for almost all pathogenic fungi.

5.3 Preclinical Studies

None known.

6.0 PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

S. NO	INGREDIENTS	GRADE
1.	BENZYL ALCOHOL	BP
2.	CETOSTEARYL ALCOHOL	BP
3.	CETOMACROGOL-1000	BP
4.	WHITE SOFT PARAFFIN	BP
5.	LIQUID PARAFFIN	BP
6.	SODIUM DIHYDROGEN PHOSPHATE	BP
7.	PEG-400	BP
8.	PURIFIED WATER	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precaution for storage

Store at temperature below 30°C. Protect from light.

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6.5 Nature contents of container

30 gm aluminum collapsible tube with screw capped in a carton

6.6 Instruction for use handling and disposal

Keep out of reach of children.

7. Manufacturer name

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