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

Registration & Regulatory Affairs (R & R) Directorate

Product Name

MC FORIS KETOCONAZOLE, CLOBETASOL PROPIONATE & NEOMYCIN SULFATE CREAM

(Ketoconazole, Clobetasol Propionate & Neomycin Sulfate 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

Each gm contains:

Ketoconazole USP 10 mg

Clobetasol Propionate USP 0.25 mg

Neomycin Sulfate USP 5000 IU

Cream Base q.s.

3. Pharmaceutical Form

Cream

4. Clinical Particulars

4.1 Therapeutic indications

The product is indicated for the topical treatment of fungal infections of the skin including Tinea Cruris, Tinea Corporis; Tinea manus, Tinea pedis, Tinea versicolor, Dermatitis, Allergic reaction such as Eczema, Prurtis.

4.2 Posology and method of administration

Dosage and Administration

Topical

Apply to the affected area two or three times daily. Generally, the duration of application depends on the type of infecting organism. Treat as below for the following:

Tinea Corporis 2 weeks

Tinea Cruris 2 weeks

Tinea Manus 4 weeks

4.3 Contraindications

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream is contra-indicated in patients with a history known sensitivity reactions to to any of its active

ingredients. It is for topical use only and cannot be used for internal or ophthalmic use. Special precaution must be observed during use on pregnant women and children.

4.4 Special warning and special precaution for use

Pseudomembranous colitis

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is less likely to occur with topically applied neomycin, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

4.5 Interaction with other medicinal products and form of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

Fertility

There are no data in humans to evaluate the effect of topical Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream on fertility. Clobetasol propionate administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose The relevance of this finding to humans has not been established.

Pregnancy

There are limited data from the use of clobetasol propionate, neomycin sulphate and miconazole in pregnant women. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development (see Pre-clinical Safety Data). The relevance of this finding to human beings has not been established. 7 Neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity. In animals has shown no teratogenic effects but is fetotoxic at high oral doses. Only small amounts of are absorbed following topical administration. Thus the use of is not recommended in pregnancy.

Lactation

The safe use of clobetasol propionate, neomycin sulphate and miconazole 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. Topically applied miconazole is minimally absorbed into the systemic circulation, and it is not known whether miconazole is excreted in human breast milk Thus use of is not recommended in lactation.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of ketoconazole, clobetasol propionate with neomycin sulphate Cream on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical ketoconazole, clobetasol propionate with neomycin sulphate Cream.

4.8 Undesirable effects

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10); common (≥1/100 and Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10); common (≥1/100.

4.9 Overdose

Symptoms and Signs Topically applied clobetasol propionate may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may appear.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The active ingredient of Cream is ketoconazole, a pyrrolidine antifungal agent. It has extremely potent anti-mycotic actions against dermatophytes and yeasts (candidiasis, Pityrosporum sabour, Torulopsis, Cryptococcus), histoplasmosis capsulalum, Eumycetes. However, the product has weak inhibitory action to Aspergillus, Sporothrix schenckii, dematiaceous fungi and mucor except for Entomophthorales. Action mechanism of Ketoconazole: it can selectively inhibit the cytochromes P-450 activity of fungi. Therefore, the Biosynthesis of Ergosterol on the cell membrane is inhibited. Clobetasol Propionate is a hormone of the cortex that is highly effective anti-inflammation and capillary contraction. Neomycin Sulfate, external use aminoglycoside antibiotics, can treat local infection.

5.2 Pharmacokinetic properties

Ketoconazole which is applied to the chest, back and buttocks of the healthy volunteers cannot be inspected in blood (Detectable Limit is less than 5ng/ml) during the first 72 hours.

Clobetasol Propionate can be completely absorbed by derma. The administered dose is metabolized, primarily in the liver. And it is excreted by kidney.

Neomycin Sulfate can be rarely absorbed by derma. However, when the skin is ulcer and breakage it can be absorbed increasingly.

5.3 Preclinical Studies

Non-clinical studies have not been conducted with Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream. Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream individually have been evaluated in animal toxicity tests, and the following statements reflect the information available on the individual components.

6. PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

1.	Propylene Glycol	BP
2.	Cetomacrogol 1000	BP
3.	Cetostearyl Alcohol	BP
4.	Sodium Sulfite	BP
5.	Polysorbate 80	BP
6.	Chlorocresol	BP
7.	Dimethyl Sulfoxide	USP
8.	Butylated Hydroxytoluene	BP
9.	Butylated Hydroxyanisole	BP
10.	White Soft Paraffin	BP
11.	Light Liqiud Paraffin	BP
12.	Purified Water	BP

6.2 Incompatibilities

Not applicable.

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6.3 Shelf life

36 months

6.4 Special precaution for storage

Store at a temperature not exceeding 30°C. Protect from light.

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

No special requirements.

7. Manufacturer name

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