1.6 PRODUCT INFORMATION

1.6.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT
MYCOMIN (Beclomethasone Dipropionate, Neomycin Sulfate & Miconazole Nitrate Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Beclomethasone Dipropionate USP…….0.025% w/w
Neomycin Sulfate BP……0.5% w/w
Miconazole Nitrate BP……..….2.0% w/w
Cream base……..q.s.

3. PHARMACEUTICAL FORM
Cream.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
MYCOMIN Cream contains the active compound Beclomethasone Dipropionate (a synthetic corticosteroid), Miconazole Nitrate and Neomycin for topical dermatologic use.
Beclomethasone Dipropionate is an anti-inflammatory, synthetic, halogenated steroid having the chemical name, 9-Chloro-11(beta), 17,21-trihydroxy-16(beta)- methylpregna-1, 4-diene-3, 20- dione 17,21-dipropionate.
Neomycin sulphate, an aminoglycoside antibiotic, is the sulphate salt of neomycin B and C, produced by the growth of Streptomyces fradiae.
Miconazole interacts with 14-α demethylase, a cytochrome P-450 enzyme necessary to convert lanosterol to ergosterol. As ergosterol is an essential component of the fungal cell membrane, inhibition of its synthesis results in increased cellular permeability causing leakage of cellular contents.
MYCOMIN Cream is indicated for the relief of the inflammatory manifestations of corticosteroid responsive dermatoses 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: Chronic dermatitis of the extremities, balanoposthitis, eczematoid dermatitis, contact dermatitis, follicular dermatitis, parakeratosis, paronychia, anal pruritus, intertrigo, impetigo, neurodermatitis, angular stomatitis, photosensitivity dermatitis, lichenified inguinal dermatophytosis and tinea infections such as tinea pedis, tinea cruris and tinea corporis. As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

4.2 Posology and method of administration
Topical Administration (Administered via Skin)
Adults and children over the age of 12 years
Topical administration. Application to the affected area usually one to three times daily or as directed by the physician
A small quantity of MYCOMIN 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.
Duration of therapy should be determined by patient response. In cases of tinea pedis, longer therapy (2 - 4 weeks) may be necessary.

4.3 Method of administration
Wash your hands before and after applying Beclomethasone Dipropionate, Neomycin Sulfate & Miconazole Nitrate Cream. Clean and dry the skin area to be treated.

4.4 Contraindications
MYCOMIN Cream is contraindicated in those patients with a history of sensitivity to any of its components or to other corticosteroids or imidazoles.
If irritation or sensitisation develops with the use of MYCOMIN Cream, treatment should be discontinued and appropriate therapy instituted.
MYCOMIN Cream is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and bacterial or viral infections.
MYCOMIN Cream is contraindicated in those patients with a history of sensitivity reactions to any of its components.
Use in pediatric patients under 12 years of age is not recommended.

4.5 Interaction with other medicinal products and other forms of interaction
No formal drug-drug interaction studies have been performed with MYCOMIN cream

4.6 Pregnancy and Lactation
Pregnancy:
Pregnancy & Nursing Mothers: Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients. Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:
Safety and effectiveness of MYCOMIN Cream in pediatric patients have not been established. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
There was no evidence of carcinogenicity in the study conducted in rats. Studies to assess the mutagenic potential of beclomethasone dipropionate have not been conducted. Impairment of fertility, as evidenced by inhibition of the estrous cycle in dogs, was observed following treatment by the oral route at a dose of 0.5 mg/kg/day.

4.7 Effects on ability to drive and use machines
Not Relevant

4.8 Undesirable effects
Adverse reactions reported for Lotriderm include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection. Reported 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) and sensitisation. In children receiving topical corticosteroids, Hypothalamicpituitary adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension.

4.9 Overdose

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress hypothalamicpituitary- adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease. Excessive or prolonged use of topical antibiotics may lead to overgrowth of nonsusceptible organisms in lesions. Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised. If overgrowth by non-susceptible organisms occurs, stop treatment with MYCOMIN Cream and institute appropriate therapy

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Beclomethasone Dipropionate : Unbound corticosteroids cross cell membranes and bind with high affinity to specific cytoplasmic receptors. The result includes inhibition of leukocyte infiltration at the site of inflammation, interference in the function of mediators of inflammatory response, suppression of humoral immune responses, and reduction in edema or scar tissue. The antiinflammatory actions of corticosteroids are thought to involve phospholipase A2 inhibitory proteins, lipocortins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes. For the investigated use in the treatment of GvHD or Crohn's, beclometasone acts by binding to interleukin-13 to inhibit cytokines, which in turn inhibits inflammatory chemicals downstream.

Pharmacodynamics Beclomethasone 17,21-dipropionate is a diester of beclomethasone which has potent glucocorticosteroid and weak mineralocorticosteroid activity. The mechanism for the anti-inflammatory action of beclomethasone dipropionate is unknown. It is postulated that topical steroids control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Corticosteroids are also thought to act by the induction of phospholipase A2 inhibitory proteins.

Miconazole is an anti-fungal medication related to Azole. Miconazole prevents fungal organisms from producing vital substances required for growth and function. This medication is effective only for infections caused by fungal organisms. It will not work for bacterial or viral infections

Neomycin is an aminoglycoside antibiotic. Aminoglycosides work by binding to the bacterial 30S ribosomal subunit, causing misreading of t-RNA, leaving the bacterium unable to synthesize proteins vital to its growth. Aminoglycosides are useful primarily in infections involving aerobic, Gram-negative bacteria, such as Pseudomonas, Acinetobacter, and Enterobacter. In addition, some mycobacteria, including the bacteria that cause tuberculosis, are susceptible to aminoglycosides. Infections caused by Gram-positive bacteria can also be treated with aminoglycosides, but other types of antibiotics are more potent and less damaging to the host. In the past the aminoglycosides have been used in conjunction with penicillin-related antibiotics in streptococcal infections for their synergistic effects, particularly in endocarditis. Aminoglycosides are mostly ineffective against anaerobic bacteria, fungi and viruses.

Neomycin acts on bacteria by interfering with bacterial protein synthesis by binding to 30s 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. Anaerobic bacteria are resistant. Staphylococcus aureus and Staph. epidermidis are highly sensitive, but all streptococci are relatively resistant.

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, 2 including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
- Cetomacrogol Emulsifying Wax
- Cetostearyl Alcohol
- Propylene Glycol
- Light Liquid Paraffin
- Disodium Edetate
- Chlorocresol
- Sodium Metabisulphite
- Purified Water

6.2 Incompatibilities
Not applicable

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store at a temperature not exceeding 30^0 C. protect from light.
Do not freeze.
Keep Medicine Out of Reach of Children

6.5 Nature and contents of container
The cream is filled into laminated tubes with internal lacquer coating and HDPE screw-on caps and enclosed in an outer carton. Pack sizes available are 15g.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER
Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION
Not Applicable