MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal Product

MeMyCo Plus

(Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream)

2. Qualitative and quantitative composition

Clotrimazole USP……1.0%w/w

Betamethasone Dipropionate USP

Equivalent To Betamethasone …….0.05%w/w

Neomycin Sulfate USP ……...0.5%w/w

Cream Base……Q. S

3. Pharmaceutical form

Cream

White to off white cream

4. Clinical particulars

4.1 Therapeutic indications

This is a combination of three medicines: Betamethasone, Clotrimazole and Neomycin. Betamethasone is a steroid which blocks the production of certain chemical messengers (prostaglandins) that make the skin red, swollen and itchy. Clotrimazole is an antifungal which stops the growth of fungi while Neomycin is an antibiotic which stops bacterial growth in the skin. Together, they treat your skin infection effectively.

This combination medication is used to treat a variety of inflamed fungal skin infections such as ringworm, athlete's foot, and jock itch. This product contains 3 medications. Clotrimazole is an azole antifungal that works by preventing the growth of fungus. Betamethasone is a strong corticosteroid that works by reducing the swelling, redness, and itching that occurs in the skin infection. Neomycin sulfate is a broad-spectrum antibacterial, antibiotic.

Hence Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream effectively controls inflammatory disorders superadded with bacterial and /or fungal infections of the skin.

4.2 Posology and method of administration

Posology

There is no separate dosage schedule for the young or elderly.

The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.

If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream.

Treatment should be continued for at least one month for dermatophyte infections, or for at least two weeks for candidal infections.

Method of administration

4.3 Contraindications

Hypersensitivity to Clotrimazole, Neomycin Sulfate and Betamethasone Dipropionate. Patients with any known previous hypersensitivity reaction to any of these ingredients should not use this preparation.

Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream is contraindicated in those patients with a history of sensitivity to any of its components or to other corticosteroids antibacterial or imidazoles.

If irritation or sensitisation develops with the use of Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream, treatment should be discontinued and appropriate therapy instituted.

It is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and viral infections.

4.4 Special warnings and precautions for use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin and in flexures. If used on the face, courses should be limited to 5 days.

CLOTRIMAZOLE, BETAMETHASONE DIPROPIONATE NEOMYCIN SULFATE CREAM SHOULD NOT BE USED WITH OCCLUSIVE DRESSING.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalised pustular

psoriasis and local and systemic toxicity due to impaired barrier function of the skin.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.

Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream is not intended for ophthalmic use.

Paediatric population

• Long term continuous therapy should be avoided in all children irrespective of age.

• Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream should not be used with adhesive dressing.

The safety and effectiveness of Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream has not been established in children below the age of 12.

If used on children, courses should be limited to 5 days.

Hypothalamic-pituitary adrenal axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 Pregnancy and lactation

Pregnancy

There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in human foetus. Hence Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream should only be used in pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

Breast-feeding

It is not known whether the components of Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Adverse reactions reported for Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream 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.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

4.9 Overdose

overdosage with topical application of Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream is unlikely and would not be expected to lead to a life-threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Toxic effects are unlikely to occur following accidental ingestion of Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal, Corticosteroid, Antibacterial

Mechanism of action:

Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, and clotrimazole which is an imidazole antifungal agent.

Topical corticosteroids are effective in the treatment of a range of dermatoses because of their anti-inflammatory anti-pruritic and vasoconstrictive actions.

Clotrimazole is a broad-spectrum antifungal agent with activity against Trichomones, Staphylococci and Bacteroides.

5.2 Pharmacokinetic

Clotrimazole, Betamethasone Dipropionate Neomycin Sulfate Cream intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action.

Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of skin and use of occlusion.

Systemically absorbed topical corticosteroids are bound to plasma proteins metabolised in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that

6. Pharmaceutical particulars

6.1 List of excipients

1. Macrogol cetostearyl ether. (N=22) BP (C.M.1000)
2. Cetostearyl Alcohol BP
3. Liquid Paraffin (Heavy) BP
4. White soft Paraffin BP (White Petroleum Jelly)
5. Propylene Glycol BP
6. Disodium Hydrogen Phosphate Dihydrate BP ($Na_2HPO_4,2H_2O$)
7. Sodium Dihydrogen Phosphate Dihydrate BP (Sodium Acid Phosphate BP)
8. Disodium EDTA BP
9. Phosphoric Acid BP
10. Perfume IHS
11. Purified Water BP

6.2 Incompatibility

Not applicable.

6.3 Shelf life

3 years

6.4 Special Precautions for Storage

Store below 30^0C in dry place. Protect from sunlight.

6.5 Nature and Contents of Container

30 g tube in a mono carton.

6.6 Special Precaution for Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Manufacturer Name:

Manufactured By: Sagar Vitaceuticals Nig. Ltd.
Plot 6, New Makun City, Sagamu,
Ogun State, Nigeria.

8. Manufactured For: Me Cure Industries PLC
Plot 6 Block H, Debo Industries Compound,
Oshodi Industrial Scheme,
Lagos, Nigeria