SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betamethasone Dipropionate, Clotrimazole, Gentamicin Sulfate Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone Dipropionate USP
equivalent to Betamethasone ..... 0.05% w/w
Clotrimazole BP ..... 1.0% w/w
Gentamicin Sulfate BP
equivalent to Gentamicin base ..... 0.1% w/w
Chlorocresol BP (As Preservative) .... 0.1% w/w
In a cream base ..... q.s.
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Topical, Semi-solid Dosage Form – Cream

4. CLINICAL PARTICULARS

4.1.Therapeutic indications

BECLOGEN is indicated for Primary irritant dermatitis, Allergic contact dermatitis, Eczema, Seborrheic dermatitis, Lichen simplex and pruritus ani. Psoriasis, Lichen Planus, Discoid lupus erythematosus, Granuloma annulare/necrobiosis lipoidica, Cutaneous leishmaniasis & Gentamicin Sulfate is used for antibacterial treatment of the skin.

4.2.Posology and method of administration:

As directed by the physician.

4.3.Contraindications

BECLOGEN Cream is contraindicated in individuals who have shown hypersensitivity to any of the components of this cream.

4.4.Special warnings and precautions for use

Long-term continuous topical therapy should be avoided where possible, particularly in children, as adrenal suppression can occur even without occlusion. If infection persists systemic chemotherapy is required. Withdraw topical corticosteroid if there is a spread of infection. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings and the skin should be cleansed before a fresh dressing is applied. Avoid prolonged application on the face. The face more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids, this must borne in mind when treating such conditions as psoriasis discoid lupus erythematosus and severe eczema if applied to the eyelids, care is need to ensure that the preparation does not enter the eye as glaucoma might result. If Betamethasone Dipropionate + Clotrimazole + Gentamicin Sulphate Cream does enter the eye, the affected eye should be bathed, in copious amounts of water. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalized postular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. Extended or recurrent application may increase the risk of contact sensitization. Extension of infection may occur due to the masking effect of the steroid. Following significant systemic absorption, aminoglycosides such as Gentamicin can cause irreversible ototoxicity; and Gentamicin has nephrotoxic potential. In renal impairment the plasma clearance of gentamicin is reduced. Products which contain antimicrobial agents should not be diluted.

Excess use of this cream is not advisable unless it is recommended by physician.

4.5.Interaction with other medicinal products and other forms of interaction

Following significant systemic absorption, Clotrimazole & Gentamicin Sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

4.6.Fertility, pregnancy and lactation

It is suitable to use in treatment of vaginal candidiasis during second and third trimester of pregnancy but, it should be avoided during First trimester as it may lead to fetal harm.

4.7.Effects on ability to drive and use machines

Not available.

4.8.Undesirable effects

Betamethasone Dipropionate

Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria. skin atrophy (bruising, shininess). Skin atrophy occurred in 3 of 63 (5%) patients, a 3-year old, a 5-year old, and a 7-year old. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Clotrimazole: Dermatologic side effects have included erythema, stinging, blistering, peeling, edema, itching, burning, and general skin irritation. Contact dermatitis, confirmed by patch testing, has been documented. Genitourinary system effects associated with intravaginal use have included burning, itching, cramping, pain, and bleeding. Vulvar lesions and rash have rarely been reported.

Gentamicin: In patients with dermatoses treated with gentamicin sulfate, irritation (erythema and pruritis) that did not usually require discontinuance of treatment has been reported in a small percentage of cases. There was no evidence of irritation or sensitization, however, in any of these patients patch-tested subsequently with gentamicin sulfate on normal skin. Possible photosensitization has been reported in several patients but could not be elicited in these patients by reapplication of gentamicin sulfate followed by exposure to ultraviolet radiation.

4.9.Overdose

Excessive or prolonged use of BECLOGEN CREAM may result in systemic absorption of steroid and complications of steroid therapy, especially growth retardation in children, suppression of pituitary adrenal function, increased susceptibility to infection, hyperglycaemia, Cushingoid state and benign intracranial hypertension. Cessation of treatment with appropriate symptomatic and supportive treatment is indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1.Pharmacodynamic properties

Betamethasone Dipropionate

The corticosteroids are a class of compounds comprising steroid hormones, secreted by the adrenal cortex and their synthetic analogs. In pharmacologic doses corticosteroids are used primarily for their anti-inflammatory and/or immunosuppressive effects. Topical corticosteroids, such as betamethasone dipropionate, are effective in the treatment of corticosteroid-responsive dermatoses primarily because of their anti-inflammatory, antipruritic, and vasoconstrictive actions. However, while the physiologic, pharmacologic, and clinical effects of the corticosteroids are well known, the exact mechanisms of their actions 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.

Clotrimazole: Clotrimazole, an azole antifungal agent, inhibits 14-α-demethylation of lanosterol in fungi by binding to one of the cytochrome P-450 enzymes. This leads to the accumulation of 14-α-methylsterols and reduced concentrations of ergosterol, a sterol essential for a normal fungal cytoplasmic membrane. The methylsterols may affect the electron transport system, thereby inhibiting growth of fungi.

Gentamicin: Gentamicin sulfate is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin. Gentamicin Sulfate Cream may clear infections that have not responded to treatment with other topical antibiotic agents. In primary skin infections such as impetigo contagiosa, treatment 3 or 4 times daily with Gentamicin Sulfate Cream usually clears the lesions promptly. In secondary skin infections, Gentamicin Sulfate Cream aids in the treatment of the underlying dermatoses by controlling the infection. Bacteria susceptible to the action of gentamicin sulfate include sensitive strains of Streptococci (group A beta-hemolytic, alpha-hemolytic), Staphylococcus aureus (coagulase positive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria, Pseudomonas aeruginosa, Aerobacter aerogenes, Escherichia coli, Proteus vulgaris, and Kiebsiella pneumoniae.

5.2.Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

5.3.Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1.List of excipients

Chlorocresol, Cetomacrogol -1000, Cetostearyl Alcohol, Light Liquid Paraffin, White Soft Paraffin, Propylene Glycol, Disodium Hydrogen Phosphate (Dihydrate), Sodium Dihydrogen Phosphate Dihydrate, Disodium Edetate, Sodium Metabisulphite, Perfume Fern Lavender (P-1).

6.2.Incompatibilities

Not Applicable.

6.3.Shelf life

36 months

6.4.Special precautions for storage

Store in a cool and dry place not above 30°C. Do not freeze. Protect from light.

Do not accept if seal is broken.Puncture nozzle seal with piercing point of the cap.

Keep the tube tightly closed after use.

Keep the medicine out of reach of children.

FOR EXTERNAL USE ONLY

6.5.Nature and contents of container

15 gm Aluminium Collapsible/Lami Tubes.

20 gm Aluminium Collapsible/Lami Tubes.

30 gm Aluminium Collapsible/Lami Tubes.

6.6.Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

M&G PHARMACEUTICALS LTD

P O BOX 1681, D 446 / 1 BANNERMAN ROAD,

(GPO) ACCRA,

GHANA

Tel # +233 302 666613

Fax # +233 302 669085

Email : mgpharm@vodafone.com.gh

8. MARKETING AUTHORISATION NUMBER(S)

FDA/SD.203-06321

9. DATE OF ~~FIRST AUTHORISATION~~/RENEWAL OF THE AUTHORISATION

17th June 2020

10. DATE OF REVISION OF THE TEXT

June 2020