

<b>GENTAPROX</b>
<b>BETAMETHASONE DIPROPIONATE, CLOTRIMAZOLE AND GENTAMICIN SULPHATE CREAM</b>
<b>MODULE 1 – ADMINISTRATIVE AND PRODUCT INFORMATION</b>

### **1.3 Product Information**

#### **1.3.1 Summary of product characteristics (SmPC)**

Enclosed-



**National Agency for Food & Drug Administration &  
Control (NAFDAC)**

**Registration & Regulatory Affairs (R & R)  
Directorate**

**SUMMARY OF PRODUCT CHARACTERISTICS  
(SmPC) TEMPLATE**

## **1. NAME OF THE MEDICINAL PRODUCT**

BETAMETHASONE DIPROPIONATE, CLOTRIMAZOLE AND GENTAMICIN SULPHATE CREAM

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Composition:

Betamethasone Dipropionate BP

Eq.to Betamethasone..... 0.05% w/w

Gentamicin Sulfate BP

Eq.to Gentamicin..... 0.10% w/w

Clotrimazole BP..... 1.00% w/w

Cream base..... q.s.

## **3. PHARMACEUTICAL FORM**

Cream

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

It 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**

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 Sulfate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

#### **4.6 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**

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

#### **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 these 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 Pharmacodynamics 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- $\alpha$ -demethylation of lanosterol in fungi by binding to one of the cytochrome P-450 enzymes. This leads to the accumulation of 14- $\alpha$ -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 Klebsiella pneumonia

### **5.2 Pharmacokinetic properties**

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**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Cetomacrogol 1000 BP

Cetostearyl Alcohol BP

Light Liquid Paraffin BP

Snow white Petroleum Jelly BP

Propylene Glycol BP

Methyl Paraben BP

Propyl Paraben BP

EDTA Sodium BP

Lavender Colonge SS IHS

Benzyl Alcohol BP

Purified water BP

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

24 months from the date of manufacture.

### **6.4 Special precautions for storage**

Store in a cool Place. Do not Freeze

### **6.5 Nature and contents of container <and special equipment for use, administration or implantation>**

30 gm Collapsible Lami Tube

### **6.6 Special precautions for disposal <and other handling>**

No special requirements.

## **7 APPLICANT/MANUFACTURER**

**Healthcare Formulations Private Limited**

C/8, Sardar Estate, Ajwa Road,

BARODA 390019.

**Manufacturer:**

**Healthcare Formulations Private Limited**

C/8, Sardar Estate, Ajwa Road,

BARODA 390019.