



## **1.3.1**

# **Summary of Product Characteristics (SmPC)**

## **Module-1 Administrative and Product Information**

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### **1. Name of the medicinal Product**

Betamethasone, Gentamicin, Tolnaftate & Clioquinol Cream.

### **2. Qualitative and Quantitative Composition**

#### **2.1 Strength:**

**Each gm contains :**

Betamethasone Valerate BP.....0.61 mg

Gentamicin Sulphate BP .....1.00 mg

Tolnaftate BP .....10.0 mg

Clioquinol BP.....10.0 mg

Cream Base BP.....Q.S.

#### **2.2 Quantitative declaration:**

Betamethasone Valerate BP + Gentamicin Sulphate BP + Tolnaftate BP + Clioquinol BP.

### **3. Clinical Particulars**

#### **3.1 Therapeutic Indications**

For the treatment of Mix bacterial and fungus infections, Tinea infections of the skin (Ringworm), Otitis externa, Seborrhoeic dermatitis, Contact dermatitis, Eczemas, Psoriasis, Athlete's foot, Anal and Vulval puritis..

#### **3.2 Posology and Method of Administration**

Apply 2-3 times a day to the affected area or as directed by Physician.

#### **3.3 Contraindications**

Contraindicated in patients who are hypersensitive to any of the component of the drug. it is contraindicated in the treatment of herpes simplex vaccaina or varicella.

#### **3.4 Special Warnings and Special Precautions for Use**

Not safe in pregnancy. Physician should be consulted before initiating therapy with AMIDERM CREAM for nursing mothers.

Keep all medicines out of the reach of children.

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### **3.5 Interaction with other medicinal products and other forms of interaction**

None have been reported on local application Avoid using other topical medications.

### **3.6 Pregnancy and Lactation**

Not safe in pregnancy. Physician should be consulted before initiating therapy with AMIDERM CREAM for nursing mothers.

### **3.7 Effects on ability to Drive and use Machines**

Not Applicable

### **3.8 Undesirable Effects**

Generally well tolerated. Some of the rarely reported side effects are burning sensation, itching, irritation dryness folliculitis, acneiform eruptions, hypopigmentation, maceration of the skin, secondary infection skin atrophy etc.

It is generally safe, Prolong, continuous treatment may cause atrophic skin changes leading to: thinning, loss of elasticity. dilatation of superficial blood vessels, telangiectasiae and ecchymoses. Systematic absorption of corticosteroid can cause hypothalamic pituitary adrenal axis suppression manifestation of Cushing's syndrome hyperglycaemia and glucosuria.

### **3.9 Overdose**

Excessive or prolonged use of topical corticosteroids can suppress pituitary-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 lesions by non-susceptible organisms.

## **4. Pharmacological Properties**

### **4.1 Pharmacodynamics Properties**

Betamethasone valerate is a potent topical corticosteroid which exhibits anti-inflammatory and anti-allergic properties when applied to the skin and mucosa. The mechanism of action is related to causing vasoconstriction, stabilising lysosomal membranes, suppressing cell division and suppressing the immune response. Gentamicin works by binding to a specific receptor protein on the 30 S subunit of bacterial ribosomes, and interferes with an initiation complex between mRNA (messenger RNA) and the 30 S subunit, inhibiting protein synthesis. DNA

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may be misread, thus producing nonfunctional proteins; polyribosomes are split apart and are unable to synthesize protein. Tolnaftate is a potent fungicidal agent against Trichophyton mentagrophytes, Trichophyton rubrum, Microsporum canis, Epidermophyton floccosum and Malassezia furfur. Tolnaftate works by distort the hyphae and to stunt mycelial growth in susceptible organisms. Clioquinol is a topical antifungal and antibacterial agent. Clioquinol inhibit certain enzymes related to DNA replication.

### **5. Pharmaceutical Particulars**

#### **5.1 List of Excipients**

Chlorocresol  
Sodium Methyl Hydroxybenzoate  
Sodium Propyl Hydroxybenzoate  
Cetostearyl Alcohol  
Cetomacrogol 1000  
Light Liquid Paraffin  
White Soft Paraffin  
Sodium Dihydrogen Phosphate Dihydrate  
Phosphoric Acid  
Disodium E.D.T.A.  
Purified Water

#### **5.2 Incompatibilities**

Not applicable

#### **5.3 Shelf Life**

36 months (proposed)

#### **5.4 Special Precautions for Storage**

Store below 30°C. Protect from light. Do not freeze.

#### **5.5 Nature and Contents of Container**



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10 ml Clear Glass Vial USP Type - III Having 20 mm Grey Bromobutyl RFU Sterile Rubber Stopper & 20mm Blue Flip Off Seal, with One Ampoule of 10 ml Sterilized Water for Injections BP in printed carton along with package insert.

### **5.6 Special precaution for disposal and other handling**

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

## **6. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)**

### **6.1 Name and Address of Marketing Authorization Holder**

GB PHARMA LIMITED

65, Chatsworth Road, London NW2 4BG.

E-mail: [info@gbpharma.co.uk](mailto:info@gbpharma.co.uk)

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### **6.2 Name and Address of manufacturing site(s)**

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-079-41078096

Fax: +91-079-41078062

Email: [hiren@lincolnpharma.com](mailto:hiren@lincolnpharma.com)

Website: [www.lincolnpharma.com](http://www.lincolnpharma.com)

### **6.3 Marketing Authorization Number**

To be included after obtaining first registration.

### **6.4 Date of First <Registration> / Renewal of The <Registration>**

It will be applicable after registration of this product.

## **7. Date of Revision of the Text**

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**8. Dosimetry (If Applicable)**

Not Applicable

**9. Instructions for preparation of radiopharmaceuticals (if Applicable)**

Not Applicable