

**SUMMARY OP PRODCUT CHARACTERISTICS (SPC)**

## **1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT**

B-Mycin Cream (Betmethasone +Gentamycin sulphate cream)

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

Each gram contains 0.643 mg betamethasone dipropionate equivalent to 0.5 mg betamethasone and 1mg gentamicin sulfate.

For the full list of excipients, see section 6.1

## **3. PHARMACEUTICAL FORM**

Cream.

White cream

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indication:**

Treatment of impetigo, ecthyma and other localized primary bacterial skin infection with a gram-negative component and also for secondary bacterial infections complicating other pre-existing dermatoses.

### **4.2 Posology and method of administration:**

Apply a thin layer to the affected area twice daily.

Method of administration: Topical

### **4.3 Contraindication:**

Hypersensitivity to any of B-mycin components.

### **4.4 Special warnings and special precautions for use:**

1. If irritation or sensitization develops with the use of B-mycin cream, treatment should be discontinued.
2. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio.

3. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children induced low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.
4. Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.
5. Use of topical antibiotics occasionally allows overgrowth of nonsusceptible organism, including fungi. If this occurs or if irritation, sensitization or superinfection develops, treatment with gentamicin should be discontinued and appropriate therapy instituted.

Use of topical gentamicin preparations in closed hospital settings is actively discouraged.
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#### 4.5 Interaction with other FPPs and other forms of interaction:

No information available.

#### 4.6 Pregnancy and lactation:

##### *Use in pregnancy:*

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 foetus.

##### *Use in lactation:*

B-mycin cream is not recommended for use in nursing mothers.

#### 4.7 Effects on ability to drive and use machines:

No information available.

#### 4.8 Undesirable effects:

Treatment with gentamicin has produced transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment.

Reported adverse reactions with the use of topical corticosteroids include: Burning, itching, irritation, dryness, hypopigmentation and allergic contact dermatitis.

#### 4.9 Overdose:

Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency and manifestations of hypercorticism.

A single overdose of gentamicin would not be expected to produce symptoms.

Excessive prolonged use of topical gentamicin may lead to overgrowth of lesions by fungi or nonsusceptible bacteria.

Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of steroids is advised. Appropriate antifungal or antibacterial therapy is indicated if overgrowth occurs.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties:

1. Betamethasone dipropionate topically produced prompt, marked and prolonged anti-inflammatory, antipruritic and vasoconstrictive effects. Gentamicin is bactericidal against a broad spectrum of common skin pathogens to which inflammatory skin disorders may be susceptible.
2. Excessive or prolonged use of topical corticosteroids can suppress pituitary- adrenal function resulting in secondary adrenal insufficiency and manifestations of hypercorticism. A single overdose of gentamicin would not be expected to produce symptoms. Excessive prolonged use of topical gentamicin may lead to overgrowth of lesions by fungi or non-susceptible bacteria.

### 5.2 Pharmacokinetic properties:

1. Corticosteroids diffuse across cell membranes and complex with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to DNA (chromatin), and stimulate transcription of messenger RNA (mRNA) and subsequent protein synthesis of various inhibitory enzymes responsible for the anti-inflammatory effects of topical corticosteroids.
2. Bacteria susceptible to the action of gentamicin include sensitive strains of *Streptococci*, *Staphylococcus aureus*, and the gram- negative bacteria *Pseudomonas aeruginosa*, *Aerobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris* and *Klebsiella pneumoniae*.

5.3 Preclinical safety data:

No information available.

**6. PHARMACEUTICAL PARTICULARS**

6.1 List of excipients:

White Petrolatum

Stearyl Alcohol

Fractionated Coconut Oil

Dimethylpolysiloxane

Propylene Glycol

Polysorbate 60

Sorbitan Monostearate

Methyl Paraben

Propyl Paraben

Purified Water

6.2 Incompatibilities:

No information available.

6.3 Shelf life:

3 years from the date of manufacture.

6.4 Special precautions for storage:

Keep in a tight container (Aluminium tube- airtight container). Store at temperature below 30°C.

Protect from light and moisture.

6.5 Nature and contents of container:

Aluminium tube of 15g.

6.6 Instructions for use and handling and disposal:

No information available.

**7. MARKETING AUTHORIZATION HOLDER:**

Y. S. P. INDUSTRIES (M) SDN. BHD.  
Lot 3, 5 & 7, Jalan P/7, Section 13,  
Kawasan Perindustrian Bandar Baru Bangi,  
43000 Kajang, Selangor Darul Ehsan,  
Malaysia.

**8. MARKETING AUTHORIZATION NUMBER**

Y.S.P/MAL/61

**9. DATE OF FIRST AUTHORIZATION**

31<sup>st</sup> May 2018

**10. DATE OF REVISION OF THE TEXT**

28 Jul 2023