SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name : **Betaleb Cream**

1.2 Generic Name : **Betamethasone Valerate Cream BP 0.1% w/w**

1.3 Strength : **Betamethasone Valerate BP 0.1 % w/w**

1.4 Pharmaceutical Form : **Topical Cream**

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Betamethasone Valerate	BP	
eq. to Betamethasone	BP	0.1 % w/w
Chlorocresol	BP	0.1 % w/w
(as preservative)		
Cream base		q.s.

SN	Ingredients
01.	Betamethasone Valerate eq. to Betamethasone
02.	Chlorocresol
03.	Cetomacrogol Emu. Wax
04.	Liquid Paraffin (H)
05.	Propylene Glycol
06.	White Soft Paraffin (White Petroleum Jelly)
07.	Perfume Lavender Prima Compound 5029
08.	Purified Water

3. PHARMACEUTICAL FORM

Topical Cream

White coloured, smooth perfumed cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Betaleb is indicated in the treatment of severe inflammatory skin disorders such as eczemas, unresponsive to less potent corticosteroids & psoriasis.

4.2 Posology and method of administration

Child: Apply 1–2 times a day, to be applied thinly.

Adult: Apply 1–2 times a day, to be applied thinly, or as directed by the physician.

Topical corticosteroid preparations should be applied no more frequently than twice daily; once daily is often sufficient. Topical corticosteroids should be spread thinly on the skin but in sufficient quantity to cover the affected areas.

4.3 Contraindications:

Betaleb is contraindicated to use in children under 2 years. Topical corticosteroids are contra-indicated in untreated bacterial, fungal, skin lesions, in rosacea, and in perioral dermatitis; potent corticosteroids are contraindicated in widespread plaque psoriasis. It also contraindicated in those patients with a history of hypersensitivity to any of the components in the preparation. Potent corticosteroids should generally be avoided
on the face and skin flexures.

4.4 Special warnings and special precautions for use:

In children avoid prolonged use and use potent or very potent corticosteroids under specialist supervision; extreme caution is required in dermatoses of infancy. **Psoriasis:** The use of potent or very potent corticosteroids in psoriasis can result in rebound relapse, development of generalized pustular psoriasis, and local and systemic toxicity. Therefore, it should be avoided or given only under specialist supervision in psoriasis.

CSM ADVICE: Patients or carers should be given advice on how to administer corticosteroid creams and ointments. If a patient is using topical corticosteroids of different potencies, the patient should be told when to use each corticosteroid. Patients and their carers should be reassured that side effects such as skin thinning and systemic effects rarely occur when topical corticosteroids are used appropriately.

4.5 Interaction with other FPPs and other forms of Interaction

The keratolytic effect of salicylic acid facilitates the absorption of topical corticosteroids; however, excessive and prolonged use of topical preparation containing salicylic acid may cause salicylism.

4.6 Pregnancy and lactation

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Therefore, Betaleb should be used during pregnancy & lactation only if the potential benefit justifies the potential risk to the fetus.

Breast Feeding: Do not use in lactating women who are breast-feeding infants, on premature infants or newborn infants during the first three months of life. Small risk of kernicterus in jaundiced infants and of haemolysis in G6PD-deficient infants.

4.7 Effects on ability to drive and use machines

A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical use of Betamethasone Valerate.

4.8 Undesirable effects

Spread and worsening of untreated infection; thinning of the skin which may be restored over a period after stopping treatment but the original structure may never return; absorption through the skin can rarely cause adrenal suppression and even Cushing's syndrome, depending on the area of the body being treated and the duration of treatment.

4.9 Overdose

Acute overdosage is very unlikely to occur. In an event of accidental overdose of Betamethasone Valerate symptomatic treatment should be provided as prescribed by the Physician.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone Valerate, is an 'potent' corticosteroid with topical anti-inflammatory activity, which is thought to involve lipocortins, phospholipase A2 inhibitory proteins, which through inhibition of arachidonic acid. control the biosynthesis of prostaglandins and leukotrienes.

5.2 Pharmacokinetic properties

Topical corticosteroids can be absorbed through normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. 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 Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Ingredients	Spec.
Chlorocresol	BP
Cetomacrogol Emu. Wax	BP
Liquid Paraffin (H)	BP
Propylene Glycol	BP
White Soft Paraffin (White Petroleum Jelly)	BP
Perfume Lavender Prima Compound 5029	IH
Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not Freeze. Protect from light. Keep Out of reach of Children. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

15gm in an aluminum lacquered collapsible tube in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

AMD/12/2002 & AMD/6/2002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 21/01/1989.

10. DATE OF REVISION OF THE TEXT

01/01/2028