SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : Betaleb Ointment

1.2 Generic Name : Betamethasone Valerate Ointment BP

1.3 Strength : 0.1% w/w

1.4 Pharmaceutical Form: Topical Ointment

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

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

3. PHARMACEUTICAL FORM

Topical Ointment

White pr almost white translucent, perfumed ointment.

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.

4.3 Contraindications:

Topical corticosteroids are contra-indicated in untreated bacterial, fungal, or viral skin lesions, in rosacea, and in perioral dermatitis; potent corticosteroids are contraindicated in widespread plaque psoriasis. Betaleb Ointment is 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:

Use of more than 100 g per week of 0.1% preparation likely to cause adrenal suppression. Avoid prolonged use (particularly on the face), cautions applicable to systemic corticosteroids may also apply if absorption occurs following topical and local use infection, keep away from eyes, use potent or very potent topical corticosteroids under specialist supervision in psoriasis (can result in rebound relapse, development of generalised pustular psoriasis, and local and systemic toxicity).

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

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

Topical corticosteroids should be wiped off thoroughly prior to breastfeeding if they are being applied to the breast or nipple area. It should be avoided on the nipple.

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 Betaleb Ointment.

4.8 Undesirable effects

Rare: Adrenal suppression, Cushing's syndrome

Frequency not known : Acne ,contact dermatitis, hypertrichosis, irreversible striae atrophicae, irreversible telangiectasia, mild
depigmentation (may be reversible), perioral dermatitis, side-effects applicable to systemic corticosteroids may also apply if absorption occurs following topical and local use, spread and worsening of untreated infection, thinning of the skin (may be restored

over a period after stopping treatment but the original structure may never return) worsening of acne & worsening of rosacea.

Side-Effects, Further Information: In order to minimise the side-effects of a topical corticosteroid, it is important to apply it thinly to affected areas only, no more frequently than twice daily, and to use the least potent formulation which is fully effective.

4.9 Overdose

Topically applied may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur.

Treatment: In the event of overdose, it should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency. Further management should be as clinically indicated

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:Topical corticosteroid

Mechanism of action:

Betamethasone Valerate, is an **'potent'** corticosteroid with topical anti-inflammatory activity, which is thought to involve lipocortins, phospholipase A2 inhibitory proteins which, through inhibition 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

SN	Ingredients	Spec.
01.	Betamethasone Valerate eq. to Betamethasone	BP
02.	Chlorocresol	BP
03.	White Soft Paraffin (White Petroleum Jelly)	BP
04.	Cetomacrogol Emu. Wax	BP

05.	Liquid Paraffin(H)	BP
06.	Propylene Glycol	BP
07.	Benzyl Alcohol	BP
08.	Perfume Lavender Prima Comp. (5029)	IH

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not freeze.

Store at a temperature not exceeding 30^0C. Protect from light. Keep Out of reach of Children.

6.5 Nature and contents of container

15 g. in an aluminium 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

LEBEN LABORATORIES PVT. LTD.,

Business Address:

RO & Works : Plot No. L-4, Phase-III, MIDC, AKOLA–444 104 (MS), INDIA
Ph.:0091-724-2259401/02/03 & Fax:2258371
E-mail- export@lebenlab.com, qad@lebenlab.com, ra@lebenlab.com

Mumbai Off. : 11, Mahavir Mansion, 70, Trinity Street, Near Metro Cinema, MUMBAI–400 002 (MS), INDIA
Ph.: 0091-22-2207-5301, 02, Fax: 2207-5303
E-mail – mumbai@lebenlab.com.

Country : INDIA

8. MARKETING AUTHORISATION NUMBER

05361/07367/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Sep 25, 2020

10. DATE OF REVISION OF THE TEXT
