Prescribing Information (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Laeovate Cream.

1.1 Strength:

Betamethasone 0.1%w/w equivalent to Betamethasone Valerate BP.

1.2 Pharmaceutical form:

Cream for topical use.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The cream contains: Betamethasone BP (as Valerate) 0.1%w/w.
For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Cream for topical use.
White semi-solid, non-gritty cream. Packed in 15g collapsible tubes and contained in a unit box with literature insert.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Laeovate cream is indicated in various skin disorders where anti-inflammatory and allergic effects are desired. It's used for management of moderate to severe steroid-responsive inflammatory and allergic disorders where the presence or possibility of infection does not exist.
It is also used for the relief of symptoms and suppression of signs of skin disorders where less potent medication is ineffective.
Laeovate is also used in cases of severe inflammatory skin disorders such as Eczema, Psoriasis, Atopic dermatitis, Contact dermatitis and Intertrigo unresponsive to less potent corticosteroids.
In addition to the above skin disorders, Laeovate often produces dramatic suppression of skin diseases such as Infantile eczema, Dermatitis herpetiformis, Serborrhoeic dermatitis, Neuro-dermatitis and some form of Psoriasis in which inflammation is a prominent feature.

4.2 Posology and method of administration:

Laeovate is applied topically by gentle message to the affected parts. The preparation is applied thinly 2-3 times daily on the affected parts reducing the frequency of application as the condition responds or as directed by the physician.

4.3 Method of administration:

Laeovate cream is used topically.

4.4 Contraindications:

Hypersensitivity to the active substance or any of the excipients. The following conditions should not be treated with betamethasone valerate:

- Untreated cutaneous infections
- Rosacea
- Acne vulgaris
- Pruritus without inflammation
- Perianal and genital pruritus
- Perioral dermatitis

Betamethasone valerate is contraindicated in dermatoses in infants under one year of age, including dermatitis.

4.5 Special warnings and special precautions for use:

1. Laeovate should not be applied to large areas, when the skin is broken or under occlusive dressings since it may be absorbed in sufficient amount to cause systemic toxicity.
2. Laeovate is contraindicated in patients with untreated bacterial, fungal and viral skin lesions as its use may result in exacerbation of the skin condition.
3. The adverse effects occasionally associated with the preparation include thinning of the skin, spread and worsening of untreated infection, mild depigmentation and increased hair growth at the side of application.
4. Laeovate" should not be applied to ulcers of the leg and long-term topical use is best avoided, especially in children. In addition, it should not be used / or treatment or rosacea and should also not be used indiscriminately for pruritus

4.6 Paediatric population:

Betamethasone valerate is contraindicated in children under one year of age. Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults; therefore, courses should be limited to five days and occlusion should not be used. Care should be taken when using

betamethasone valerate to ensure the amount applied is the minimum that provides therapeutic benefit.

4.7 Interaction with other medicinal products and other forms of interaction:
Co-administered drugs that can inhibit CYP3A4 (e.g., ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

4.8 Additional information on special populations:
Elderly:
Clinical studies have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore, the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.
Renal / Hepatic Impairment:
In case of systemic absorption (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore, the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

4.9 Paediatric population:
Betamethasone valerate is contraindicated in children under one year of age. Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults; therefore, courses should be limited to five days and occlusion should not be used. Care should be taken when using betamethasone valerate to ensure the amount applied is the minimum that provides therapeutic benefit.

4.10 Fertility, Pregnancy & Lactation:
Fertility:
There are no data in humans to evaluate the effect of topical corticosteroids on fertility.
Pregnancy:
There are limited data from the use of betamethasone valerate in pregnant women.
Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established; however, administration of betamethasone valerate during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.
Lactation:
The safe use of topical corticosteroids during lactation has not been established.
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of betamethasone valerate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.
If used during lactation betamethasone valerate should not be applied to the breasts to avoid accidental ingestion by the infant.

4.11 Effects on ability to drive and use machines:
There have been no studies to investigate the effect of betamethasone valerate on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical betamethasone valerate.

4.12 Undesirable effects:
Adverse drug reactions (ADRs) are listed below by system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥1/10,000 and <1/1,000) and very rare (<1/10,000), including isolated reports.
Post-marketing data:

Infections and Infestations	
Very rare	Opportunistic infection
Immune System Disorders	
Very rare	Hypersensitivity, generalized rash
Endocrine Disorders	
Very rare	Hypothalamic-pituitary adrenal (HPA) axis suppression Cushingoid features (e.g., moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis.

Skin and Subcutaneous Tissue Disorders	
Common	Pruritus, local skin burning /skin pain.
Very rare	Allergic contact dermatitis /dermatitis, erythema, rash, urticaria, pustular psoriasis, skin thinning* / skin atrophy*, skin wrinkling*, skin dryness*, striae*, telangiectasias*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms.
General Disorders and Administration Site Conditions	
Very rare	Application site irritation/pain.
Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.* **Eye disorders	
Not known	Vision, blurred

Reporting of suspected reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.13 Overdose and particulars of its treatment:
Symptoms and signs:
Topically applied betamethasone valerate 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, betamethasone valerate 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 or as recommended by the national poisons centre, where available.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties:
Pharmacotherapeutic Group: Dermatologicals, Corticosteroids, Dermatological Preparations, Corticosteroids, Plain, Corticosteroids, potent (group III) betamethasone.
ATC Code: D07AC01.
Laeovate contains Betamethasone, a corticosteroid with Strong anti- inflammatory and ant allergic properties. Betamethasone exerts its anti- inflammatory effects by inhibiting cyclo-oxygenase enzymes involved in the biosynthesis of prostaglandins.
Betamethasone may be absorbed topically especially if applied to large areas of thin skin or broken skin or to raw surface.
Laeovate combines the essential anti-inflammatory and antiallergic properties of Betamethasone with the ease ·of application and comfort of product formulation making it safe, fine and suitable for topical application.

5.2 Pharmacokinetic properties:
Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption. The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary because circulating levels are well below the level of detection. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolized, primarily in the liver. Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data:
Reproductive toxicity:
Subcutaneous administration of betamethasone valerate to mice or rats at doses ≥0.1 mg/kg/day or rabbits at doses ≥12 micrograms/kg/day during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation. The effect on fertility of betamethasone valerate has not been evaluated in animals.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients:
- Chlorocresol
- Cetostearyl Alcohol
- Cetomacrogol 1000
- White Soft Paraffin
- Liquid Paraffin
- Sodium Dihydrogen Phosphate

6.2 Incompatibilities:
None Known.

6.3 Shelf life:
36 Months.

6.4 Special precautions for storage:
Store in a dry place below 30ºC.
Do not freeze.
Protect from light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container:
Packed in collapsible tubes and contained in a unit box with literature insert.

6.6 Special precautions for disposal <and other handling>:
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6.7 Distribution Category:
Prescription Only Medicine (POM).

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES
Marketing Authorization Holder:
Company Name: Laboratory and Allied Limited.
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.
Telephone: +254 20 8040306
Telefax: +254 20 8040309
E-Mail: info@laballied.com.

Manufacturing Site Address:
Company Name: Laboratory and Allied Limited.
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.
Telephone: +254 20 8040306.
Telefax: +254 20 8040309.
E-Mail: info@laballied.com

8. MARKETING AUTHORIZATION NUMBER
Kenya: Registration No. H98/114.

9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>
Date of first authorization: 09/04/1998.
Date of latest renewal: Retained Annually.

10. DATE OF REVISION OF THE TEXT
August, 2024.

11. DOSIMETRY (IF APPLICABLE)
Not Applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable.