# SUMMARY OF PRODUCTS CHARACTERISTICS

## 1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

**1.1** Brand Name : **Enderm Ointment**
**1.2** Generic Name : Clobetasol Propionate Ointment USP 0.05% w/w
**1.3** Strength : Clobetasol Propionate USP 0.05% w/w
**1.4** Pharmaceutical Form : Ointment

## 2. QUALITATIVE & QUANTITATIVE COMPOSITION :

| | | |
|---|---|---|
| Clobetasol Propionate | USP | 0.05% w/w |
| Chlorocresol (as preservative) | BP | 0.10% w/w |
| Ointment base | | q.s. |

## 3. PHARMACEUTICAL FORM

Ointment
White coloured, smooth perfumed Ointment.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Enderm is indicated for short-term treatment only of severe resistant inflammatory skin disorders such as recalcitrant eczemas unresponsive to less potent corticosteroids psoriasis.

### 4.2 Posology and method of administration

Apply thinly 1-2 times daily for upto 4 weeks.
Topical corticosteroids preparations should be applied no more frequently than twice daily; once daily is often sufficient.

**4.3 Contraindications:**

Clobetasol Propionate a topical corticosteroid is contra-indicated in untreated bacterial, fungal, viral skin lesions, rosacea, and in perioral dermatitis. Very potent topical corticosteroids should be avoided or be given only under specialist supervision in psoriasis because, although they may suppress the psoriasis in the short term, relapse or vigorous rebound occurs on withdrawal (sometimes precipitating severe pustular psoriasis). They should not be used indiscriminately in pruritus (where they will only benefit if inflammation is causing the itch) and are not recommended for acne vulgaris.

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

Avoid prolonged use of a topical corticosteroid on the face (and keep away from eyes). In children use potent or very potent corticosteroids under specialist supervision. If a reaction suggesting sensitivity or irritation occur, the treatment should be discontinued.

**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. Concurrent administration of barbiturates, carbamazepine, phenytoin, primidone or rifampicin may enhance the metabolism and reduce the effect of corticosteroids. Ethacrynic acid and perhaps frusemide may increase the risk of aminoglycoside toxicity.

**4.6 Pregnancy and lactation**

**Pregnancy:** Use should be avoided during pregnancy, unless clearly necessary. It is only recommended for use during pregnancy when there are no alternatives.
**Lactation:** Topical corticosteroids should be wiped off thoroughly prior to breast feeding if they are being applied to the breast or nipple area. It should be used if potential benefit outweigh the potential risk.

**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 preparation.

**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.

**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 & Treatment

In an accidental overdose of Clobetasol Propionate symptomatic treatment should be provided as per direction of the physician.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group:** Anti-inflammatory

**Mechanism of action:**

**Clobetasol Propionate:** A very potent synthetic topical corticosteroid, produces anti-inflammatory, antipruritic and vasoconstrictive action.

### 5.2 Pharmacokinetic properties

Topically applied Clobetasol Propionate can be absorbed through normal intact skin, are metabolized primarily in the liver. Topical corticosteroids and metabolites are excreted by the kidneys and to a lesser extent in bile.

### 5.3 Preclinical safety data

None Known

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

| SN | Ingredients | Spec. |
|---|---|---|
| 01. | Chlorocresol | BP |
| 02. | Cetomacrogol Emulsifying Wax | BP |
| 03. | Propylene Glycol | BP |
| 04. | Liquid Paraffin | BP |
| 05. | White Soft Paraffin<br>(White Petroleum Jelly) | BP |
| 06. | Perfume Lavender Prima Compound (5029) | IH |

### 6.2 Incompatibilities

Not Known

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store at a controlled room temperature (15°C to 30°C.). Do not refrigerate. Protect from Light.

**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**

For external use only.

**7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS**

**LEBEN LABORATORIES PVT. LTD.,**

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**8. MARKETING AUTHORISATION NUMBER**

**AMD/12/2002 & AMD/6/2002:**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**a) Date of first authorization: 21/01/1989.**

**b) Date of latest renewal: 01/01/2018.**

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

**01/01/2023**