Summary of Product Characteristics

1. Name of the medicinal Product

Clobetasol Cream BP 0.05 % w/w

2. Qualitative and Quantitative Composition

Qualitative declaration

Clobetasol Propionate BP

Quantitative declaration

Each gm contains 0.18 %w/w of Sodium Methyl Hydroxybenzoate, 0.09 %w/w of Sodium Methyl Hydroxybenzoate & 7.0 %w/w of Cetostearyl Alcohol.

For full list of excipients, see section 6.1.

3. Pharmaceutical Form

Topical cream
Distribution category: POM
A white to off-white colour smooth cream.

4. Clinical Particulars

1. Therapeutic Indications

Clobetasol is a very potent topical corticosteroid indicated for:

- Psoriasis (excluding wide spread plaque psoriasis)
- Recalcitrant dermatoses
- Lichen planus
- Discoid lupus erythematosus
- Other skin conditions which do not respond satisfactorily to less potent steroids.

2. **Posology and Method of Administration**

Route of administration:

Cutaneous, creams are especially appropriate for moist or weeping surfaces.
Clobetasol propionate belongs to the most potent class of topical corticosteroids (Group four) and prolonged use may result in serious side effects. If treatment with a local corticosteroid is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered. Repeated but short courses of clobetasol propionate may be used to control exacerbations.

Adults, Elderly and Children over 1 year:

Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day until improvement occurs, then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient.

If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated. Treatment should not be continued for more than 4 weeks. If continuous treatment is necessary, a less potent preparation should be used. The maximum weekly dose should not exceed 50 gms/week.

Recalcitrant dermatoses: Patients who frequently relapse: Once an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing (once daily, twice weekly, without occlusion) may be considered. This has been shown to be helpful in reducing the frequency of relapse. Application should be continued to all previously affected sites or to known sites of potential relapse. This regimen should be combined with routine daily use of emollients. The condition and the benefits and risks of continued treatment must be re-evaluated on a regular basis.

Paediatric population:

It is not recommended for used it is contraindicated in children under one year of age.

Duration of treatment for children and infants:

Courses should be limited if possible to five days and reviewed weekly. Occlusion should not be used.

Application to the face: Courses should be limited to five days if possible and occlusion should not be used.

Elderly:
Clinical studies have not identified differences in responses between the elderly and younger patients.

Renal/Hepatic Impairment:
Minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

3. Contraindications

Clobetasol is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. To treat any of the following skin problems, it could make them worse with clobetasol cream: untreated cutaneous infections, rosacea, acne vulgaris, pruritus without inflammation, perianal and genital pruritus, perioral dermatitis. It is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions.

4. Special warnings and precautions for use

Clobetasol should be used with caution in patients with a history of local hypersensitivity to other corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions may resemble symptoms of the condition under treatment.

Patients should be advised to wash their hands after applying dermolin cream unless it is the hands that are being treated.

Long-term use of clobetasol propionate beyond the recommended doses. Cases of osteonecrosis serious infections: Include necrotizing fasciitis and systemic immunosuppression have been reported. In some cases, patients used concomitantly other potent oral/topical corticosteroids or immunosuppressors (e.g. methotrexate, mycophenolate mofetil). If treatment with local corticosteroids is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered.

Manifestations of hypercortisolism (cushing's syndrome), reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids.

If either of the above sign are observed, withdraw the drug gradually by reduce the frequency of application, or by substituting a less potent corticosteroid. Sudden withdrawal of treatment may result in glucocorticosteroid insufficiency.

Patient should warn and take special precaution for using the clotrimazole 0.05% cream it contains excipients with known effect: methyl hydroxybenzoate, propyl hydroxybenzoate, cetostearyl alcohol and chlorocresol.

Excipients with known effect:
Methyl hydroxybenzoate, propyl hydroxybenzoate: may cause allergic reactions (possibly delayed), cetostearyl alcohol: may cause local skin reactions (e.g. contact dermatitis), and chlorocresol: may cause allergic reactions.

Risk factors for increased systemic effects are:
Potency and formulation of topical steroid, duration of exposure.
Application to a large surface area, use on occluded areas of skin, increasing hydration of the stratum corneum.

Use on thin skin areas such as the face, use on broken skin or other conditions where the skin barrier may be impaired.

In comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects.

Paediatric population: In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur. Children are more susceptible to develop atrophic changes with the use of topical corticosteroids.

Duration of treatment for children and infants: Courses should be limited if possible to five days and reviewed weekly. Occlusion should not be used.

Infection risk with occlusion: Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Use in Psoriasis: Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Concomitant infection: Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Chronic leg ulcers: Patient should take precaution using for a chronic leg ulcer, may be at increased risk of local allergic reaction or infection.

Application to the face: Patient should take precaution while applying to thin skin such as the face, as dermolin may cause skin thinning. Use on the face should be limited to 5 days. Dressings or bandages should not be used on the face where the cream is applied.

Application to the eyelids: Patient should take precaution if they applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye. If clobetasol does enter the eye, the affected eye should be bathed in copious amounts of water.

Visual disturbance: has been reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy which have been reported after use of systemic and topical corticosteroids.
It contains paraffin. Instruct patients not to smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Pregnancy: There are limited data from the use of clobetasol in pregnant women. It should be used during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the fetus. The minimum quantity should be used for the minimum duration.

Breast-feeding: The safe use of topical corticosteroids during lactation has not been established.

It is not known corticosteroids could be excreted in breast milk. It should only be use during lactation considered if the expected benefit to the mother outweighs the risk to the infant. If used during lactation clobetasol should not be applied to the breasts to avoid accidental ingestion by the infant.

5. Interaction with other medicinal products and other forms of interaction

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir and itraconazole), inhibits 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.

6. Pregnancy and Lactation

Pregnancy: There are limited data from the use of clobetasol in pregnant women. It should be used during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the fetus. The minimum quantity should be used for the minimum duration.

Breast-feeding: The safe use of topical corticosteroids during lactation has not been established. It is not known corticosteroids could be excreted in breast milk. It should only be use during lactation considered if the expected benefit to the mother outweighs the risk to the infant. If used during lactation clobetasol should not be applied to the breasts to avoid accidental ingestion by the infant.

7. **Effects on ability to Drive and use Machines**

Effects on ability to drive and use machine is not known

8. Undesirable effect

Adverse drug reactions related to Clobetasol Cream are listed below:
Common: Pruritus, local skin burning/ Skin pain
Uncommon: Skin atrophy, striae, telangiectasias
Very rare: Opportunistic infection, Hypersensitivity, generalised rash, Hypothalamic-pituitary adrenal (HPA) axis suppression (Cushingoid features, delayed weight gain/ growth, retardation in children, osteoporosis, glaucoma, hyperglycaemia/ glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis), Skin thinning, skin wrinkling , skin dryness , pigmentation changes , hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis/ dermatitis, pustular psoriasis, erythema, rash, urticaria, acne, Application site irritation/pain.
Not known: Vision, blurred.

9. Overdose

Symptoms:

Topically applied clobetasol 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.

Management:

In the event of overdose, clobetasol should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacotherapeutic Group: Topical Corticosteroids
ATC Code: D07AD01
Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties. Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

5.2 Pharmacokinetic Properties

Absorption: 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.

Distribution: The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Metabolism: Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination: It is excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical Safety Data

Not Applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Chlorocresol BP
Sodium Methyl Hydroxybenzoate BP
Sodium Propyl Hydroxybenzoate BP
Cetostearyl Alcohol BP
White Soft Paraffin BP
Light Liquid Paraffin BP
Cetomacrogol 1000 BP
Phosphoric Acid BP
Disodium Edetate BP
Purified Water BP

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months
The product should not be used more than 28 days after the opening of the tube

6.4 Special Precautions for Storage

Do not Store above 30°C. Protect from light. Do not freeze.

6.5 Nature and contents of container

A white to off-white color smooth cream filled in 30 gm Aluminum Collapsible Tube. Such 1 Tube is packed in Printed Carton with Packing Insert.

A white to off-white color smooth cream filled in 15 gm Aluminum Collapsible Tube. Such 1 Tube is packed in Printed Carton with Packing Insert.

6.6 Special precautions for disposal and other handling

Dispense in a tight, with a child-resistant closure.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, **India.**
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

7.2 Name and Address of Manufacturing Site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, **India.**

Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

8 Marketing Authorization Number
TAN 22 HM 0043

9 Date of First <Registration> / Renewal of The <Registration>
10/01/2022

10 Date of Revision of the Text