1. Name of the medicinal Product

Betamethasone Dipropionate Cream USP 0.05 % w/w

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Betamethasone Dipropionate USP eq. to Dipropionate

2.2 Quantitative declaration

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

It is a synthetic fluorinated corticosteroid. It is active topically and produces a rapid and sustained response in eczema and dermatitis of all types, including atopic eczema, photodermatitis, lichen planus, lichen simplex, prurigo nodularis, discoid lupus erythematosus, necrobiosis lipoidica, pretibial myxoedema and erythroderma. It is also effective in the less responsive conditions such as psoriasis of the scalp and chronic plaque psoriasis of the hands and feet, but excluding widespread plaque psoriasis.

2. Posology and Method of Administration

Adults and Children:

Once to twice daily. In most cases a thin film of Betamethasone Dipropionate Cream should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application.

Betamethasone Dipropionate Cream is especially appropriate for moist or weeping surfaces and the ointment for dry, lichenifield or scaly lesions but this is not invariably so.

Control over the dosage regimen may be achieved during intermittent and maintenance therapy by using Diprobase Cream or Ointment, the base vehicles of Betamethasone Dipropionate Cream and Ointment. Such control may be necessary in mild and improving dry skin conditions requiring low dose steroid treatment.

3. Contraindications

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the cream formulation. Also in tuberculous and most

viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. It should not be used in napkin eruptions, fungal or bacterial skin infections without sui table concomitant anti-infective therapy.

4. Special Warnings and Special Precautions for Use

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Occlusion must not be used.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

General: Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, treatment should be discontinued and appropriate therapy instituted.

Betamethasone Dipropionate Cream is not for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient present 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 of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric population:

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than adult patients because of greater absorption due to a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

Instruct patients not to smoke or go near naked flames – 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.

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

There are non stated significant interactions

6. Fertility, Pregnancy and Lactation

There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

7. Effects on ability to Drive and use Machines

Effects on ability to Drive and use Machines are non stated.

8. Undesirable Effects

Betamethasone Dipropionate Cream skin preparations are generally well tolerated and side-effects are rare. The systemic absorption ofbetamethasone dipropionate may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.

The following local adverse reactions that have been reported with the use of Betamethasone Dipropionate Cream include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral

dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

Vision blurred has been reported with corticosteroid use

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the TMDA ADR reporting tool; website: https:// imis.tmda.go.tz/arrt or search for TMDA Adverse Reactions Reporting Tool in the Google Play Store;

9. Overdose

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency. In such cases appropriate symptomatic treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid.

The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. Pharmacological Properties

1. Pharmacodynamics Properties

Pharmacotherapeutic Group: Topical Corticosteroids

ATC Code: D07AC01

Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions. The mechanism of anti -inflammatory activity of the topical corticosteroids is unclear. It control s the rate of protein synthesis; depresses the migration of polymorphonuclear leukocytes, fibroblasts; reverses capillary permeability and lysosomal stabilization at the cellular level to prevent or control inflammation.

2. Pharmacokinetic Properties

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

3. Preclinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical Particulars

1. List of Excipients

Cetomacrogol 1000
Chlorocresol
Propylene Glycol
Light Liquid Paraffin
White Soft Paraffin
Sodium Dihydrogen Phosphate Dihydrate
Cetostearyl Alcohol
Purified Water

2. Incompatibilities

Not applicable.

3. Shelf Life

36 months

The Product should not be Use more than 28 days after the opening of the tube.

4. Special Precautions for Storage

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

5. Nature and Contents of Container

15 gm printed Aluminium Collapsible tube packed in printed carton and packaging insert.

6. Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

2. Marketing Authorization Holder and Manufacturing Site Addresses

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
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

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
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

8. **Marketing Authorization Number**

TAN 22 HM 0180

9. **Date of First <Registration> / Renewal of The <Registration>**

04th May, 2022

10. **Date of Revision of the Text**