SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

BETAMBIL (Betamethasone Dipropionate Cream USP**)**

2. Qualitative and quantitative composition

Betamethasone Dipropionate USP..... 0.05%w/w
Cream Base .....q.s

3. Pharmaceutical form

A White Soft mass filled in Printed Aluminum/Laminated tube.

4. Clinical particulars

4.1 Therapeutic indications

Betamethasone Dipropionate 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 myxodemea 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.

4.2 Posology and method of administration

Posology

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, lichen field or scaly lesions but this is not invariably so.

Control over the dosage regimen may be achieved during intermittent and maintenance therapy by using Betamethasone Dipropionate 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.

Method of administration

For Topical use.

For the 0.05% lotion, apply a few drops to the affected skin area(s) and massage lightly until it disappears. Apply twice daily, in the morning and at night. AUGMENTED products (i.e., betamethasone dipropionate 0.05% gel, lotion, cream or ointment in augmented base) are applied once or twice daily.

4.3 Contraindications

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the Betamethasone Dipropionate presentations contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vacinia, varicella. Betamethasone Dipropionateshould not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

4.4 Special warnings and 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 generalisedpustular 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 is not for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 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.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions are known with the topical forms of terbinafine.

4.6 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.

4.7 Effects on ability to drive and use machines
None stated.

8 Undesirable effect
Betamethasone Dipropionate cream skin preparations are generally well tolerated and side-effects are rare. The systemic absorption of betamethasone 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 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 (frequency not known).

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard

4.9 Overdose

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. 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.

Symptoms

unusual/extreme tiredness, weight loss, headache, swelling ankles/feet, increased thirst/urination, vision problems. A very serious allergic reaction to this drug is rare.

Treatment

Betamethasone topical cream, gel, lotion, and ointment are used to help relieve redness, itching, swelling, or other discomforts caused by certain skin conditions. Betamethasone topical spray is used to treat adults with mild to moderate plaque psoriasis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: anti-inflammatory for topical use (ATC code D07XC01)
Corticosteroids bind to the glucocorticoid receptor inhibiting pro-inflammatory signals, while promoting anti-inflammatory signals.Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces. Patients who require long-term treatment with a corticosteroid should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections.

5.2 Pharmacokinetic properties

Absorption of topical corticosteroids depends on several factors such as the vehicle, or delivery system used by the drug, the integrity of the epidermal barrier, and whether or not an occlusive bandage is used in combination with the drug.
The absorption of topical betamethasone dipropionate is theoretically minuscule; however, if absorbed it follows the same pharmacokinetic profile that is typical of systemic corticosteroids. It is metabolized primarily by the liver by hydrolysis to its metabolites B17P (primary) and betamethasone and the 6β-hydroxy derivatives of those metabolites, and it is excreted primarily by the kidneys.

5.3 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

6.1 List of excipients

Betamethasone Dipropionate
Cetomacragol 1000
Cetostearyl Alcohol
Propylene Glycol

Light Liquid Paraffin
Disodium EDTA
Chlorocresol
Sodium Metabisulphate
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C. Do not freeze.

6.5 Nature and contents of container

A White soft mass filled in printed lami tube

Pack size: - 15gm

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorization holder

Curetech Skincare

Plot No.32, 33 & 34,
Phase–IV, Bhatoli Kalan
Baddi, Distt. Solan (HP)

8. Marketing authorisation number(s)

MNB/06/406

09444/10460/NMR/2022

9. Date of first authorization/renewal of the authorisation

Jan 25, 2024

10. Date of revision of the text

Not applicable