SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Beclometasone dipropionate 0.25 mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 0.25 mg beclometasone dipropionate

Excipients with known effect:

Each gram of cream contains 1 mg of chlorocresol and 72 mg cetostearyl alcohol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

A smooth white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Beclometasone dipropionate Cream is indicated for the treatment of the various forms of eczema in children and adults including atopic and discoid eczemas; primary irritant and allergic dermatitis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses including lichen simplex; intertrigo; discoid lupus erythematosus.

The cream is often appropriate for moist or weeping surfaces and the ointment for dry, lichenified or scaly lesions but this is not invariably so.

4.2 Posology and method of administration

Posology

Beclometasone dipropionate Cream should be applied thinly over the whole of the affected area and gently rubbed in. Initially, application should be made twice daily, but when improvement is seen, the intervals between applications may be extended and treatment eventually stopped. If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral may be necessary. After cessation of treatment, should the condition recur, twice daily treatment should be re-instituted. However, when improvement is seen again, the intervals between applications may be gradually extended until maintenance dosing of application every third or fourth day is achieved. This is likely to avoid subsequent reappearance of the condition.

The beneficial effects may be enhanced by preliminary use of hot soaks, or by intermittent applications or occlusive dressings.

Method of administration

For topical administration

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

The cream should not be applied to the eyes. Rosacea, acne vulgaris; perioral dermatitis. Primary cutaneous viral infections (e.g. herpex simplex, chickenpox). Hypersensitivity to the preparation. Varicose ulcers or any other stasis ulcers.

Use of Beclometasone dipropionate Cream is not indicated in the treatment of primarily infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo); primary or secondary infections due to yeasts; perianal and genital pruritus; dermatoses in children under 1 year of age, including dermatitis and napkin eruptions.

4.4 Special warnings and precautions for use

Long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.

If used in childhood, or on the face, courses should be limited if possible to five days and occlusion should not be used.

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

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

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 systemic administration of antimicrobial agents.

Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

Visual disturbance

Visual disturbance may be 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 (CSCR) which have been reported after use of systemic and topical corticosteroids.

Fire hazard in contact with dressings, clothing and bedding

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.

Excipients

This medicine contains chlorocresol and cetostearyil alcohol.

Chlorocresol may cause allergic reactions.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

The label will state moderate steroid.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

4.7 Effects on ability to drive and use machines

Beclometasone dipropionate 0.25 mg/g cream has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Eye disorders

Not known (cannot be estimated from the available data): Vision, blurred (see also section 4.4).

Skin and Subcutaneous Tissue Disorders

Not known (cannot be estimated from available data): Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as thinning, striae, and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

As with other topical corticosteroids, prolonged used of large amounts, or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercorticism. The effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the napkin may act as an occlusive dressing.

Should systemic corticosteroid effects arise from application of Beclometasone dipropionate Cream, topical treatment should be discontinued. If adrenal function is impaired the patient will need to be protected from any harmful effects of stress with oral corticosteroid preparations until normal adrenal function is established.

There are reports of pigmentation changes and hypertrichosis with topical steroids.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease (see precautions).

Beclometasone dipropionate Cream is usually well tolerated, but if signs of hypersensitivity appear, application should stop immediately. Exacerbation of symptoms may occur.

Reporting of suspected adverse 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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Should systemic corticosteroid effects arise from application of Beclometasone dipropionate Cream topical treatment should be discontinued. If adrenal function is impaired the patient will need to be protected from any harmful effects of stress with oral corticosteroid preparations until normal adrenal function is established.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, potent (group III), ATC code: D07AC15.

Beclometasone dipropionate is an active corticosteroid with topical anti-inflammatory activity.

5.2 Pharmacokinetic properties

Absorption

The extent of percutaneous absorption of topical corticosteroid is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Distribution

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systematically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees.

Biotransformation

Corticosteroids are metabolised primarily by the liver.

Elimination

Topical corticosteroids are excreted by the kidneys.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol

Cetomacrogol 1000

Cetostearyl Alcohol

White Soft Paraffin

Liquid Paraffin

Sodium Acid Phosphate

Phosphoric Acid

Sodium Hydroxide

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25 ºC. Store in the original package in order to protect from light.

6.5 Nature and contents of container

Collapsible aluminium tubes internally coated with an epoxy resin based lacquer, and closed with a wadless polypropylene cap.

Pack size: 15g, 30g, 50g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Ltd,

Trading as Essential Generics,

8a Crabtree Road,

Egham, Surrey

TW20 8RN

8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0127

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 June 1999

10 DATE OF REVISION OF THE TEXT

16/10/2025