

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

BETASOL CREAM (Clobetasol Propionate Cream USP)

2. Qualitative and quantitative composition

Betasol cream contains Clobetasol Propionate Cream USP 0.05% w/w For a full list of excipients, see section 6.1

3. Pharmaceutical form

Cream (Topical Preparation)

4. Clinical particulars

4.1 Therapeutic indications

Betasol is indicated for the treatment of the following situations: -

Psoriasis (excluding widespread plaque psoriasis);

- Resistant forms of eczema;

- Contact dermatitis;

- Seborrheic dermatitis;

- Lichen planus;

- Discoid lupus erythematosus;

- other dermal conditions that do not respond satisfactorily to less active steroids.

4.2 Posology and method of administration

Apply the minimum amount necessary to the affected area once or twice a day. Discontinue therapy when it obtains control of the situation. Treatment should not continue for more than 4 weeks without the patient being reassessed. Betasol can be used in treatment cycles repeated short-term to control exacerbations. If continuous steroid treatment is required, use a less potent formulation. Betasol is potent, so treatment should be limited to two consecutive weeks and amounts not greater than 50g a week should be used because of the potential that the drug has to suppress the hypothalamic- pituitary- adrenal. If necessary, in very resistant lesions, especially in case of hyperkeratosis, the anti- inflammatory action of Betasol may be enhanced by occlusion of the area to be treated with a polyethylene film. It is usually sufficient for an occlusion overnight to yield a satisfactory response, and the improvement attained can be kept up with topical application without occlusion.

Betasol Cream: Apply a small amount to the affected area and massage.

Route of Administration: Cream (Topical Preparation)

4.3 Contraindications

Betasol is contraindicated in the following situations: Hypersensitivity to the active substance or to any of the excipients; rosacea; acne vulgaris; perioral dermatitis; perianal and genital pruritus; Primary cutaneous viral infections (e.g. Herpes simplex, chickenpox); treatment of primary cutaneous lesions caused by fungi or bacteria; dermatoses in children under 12 years of age, including dermatitis and rash caused by diapers.

The long-term therapy is contraindicated in patients with diabetes mellitus or tuberculosis.

4.4 Special warnings and precautions for use

Pregnancy

- Betasol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers

- Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

Paediatric Use

- HPA axis (hypothalamic-pituitary-adrenal axis) suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

None have been reported on local application. Avoid using other topical medications, harsh or abrasive soaps, or cosmetics on the affected area.

4.6 Pregnancy and Lactation

Use in Fertility

- There are no data in humans to evaluate the effect of topical corticosteroids on fertility

Use in Pregnancy

- Betasol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in nursing mothers

- In nursing mothers systemically, administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Local hypersensitivity reactions may occur such as erythema, rash, pruritus, urticaria, itching and located allergic contact dermatitis that may resemble the symptoms of the disease. If signs of hypersensitivity reactions should be discontinued immediately the application. Effects of hypercortisolism. Like other topical corticosteroids, prolonged use of large amounts or treatment may result in large areas sufficient to produce the effect of systemic absorption hypercortisolism. This effect is most likely to occur in infants and children, and if used with occlusive dressings. In infants, the diaper may act as an occlusive dressing.

In adults, providing that total less than 50 g weekly dose. Prolonged and

intensive treatment with very potent formulations of corticosteroids can cause dilation of superficial blood vessels, particularly when occlusive dressings are used or skin folds are involved. Local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of symptoms underlying pustular psoriasis. Prolonged and intensive treatment with very potent formulations of corticosteroids can cause local atrophic changes such as thinning, stretch marks, particularly when used dressings or skin folds are involved. It is suspected that, in very rare cases, the treatment of psoriasis with corticosteroids (or its suspension) have provoked the pustular form of the disease.

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 Pharmacy and Poisons Board- Pharmacovigilance Electronic Reporting System (PvERS); <https://pv.pharmacyboardkenya.org> .

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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacological category: Corticosteroids, very potent (group IV)

ATC Code: D07AD

Pharmacodynamic properties

Betasol is local anti-inflammatory drug acting on skin and mucous membranes. Betasol acts by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

5.2 Pharmacokinetic properties

The percutaneous penetration of clobetasol propionate vary individually and can be increased by the use of occlusive dressings, or when the skin is inflamed or damaged. In a study of healthy individuals and healthy skin, the mean maximum plasma concentration of clobetasol propionate 0.63 mg /mL occurred eight hours after the second application (13 hours after initial application) 30 g of ointment clobetasol propionate 0.05%.

After application of a second dose of 30 g of Clobetasol propionate cream 0.05%, the mean maximum plasma concentration was slightly higher than that of the ointment and took place 10 hours after application. In another study, the mean maximum plasma concentration was about 2.3 mg / ml and 4.6 ng / ml in patients with psoriasis and eczema, respectively, and was 3 hours after a single application of 25 g ointment propionate Clobetasol 0.05%. Upon the percutaneous absorption of clobetasol propionate, probably the drug followed the metabolic pathway of systemically administered corticosteroids. However, clobetasol systemic metabolism is not fully characterized or quantified.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

BSHS

Cetomacrogol 1000 BP

Cetostearyl Alcohol BP

Methyl hydroxybenzoate BP

Propyl hydroxybenzoate BP

White soft Paraffin BP

Chlorocresol BP

Propylene Glycol BP

Sodium Dihydrogen Phosphate BP

Purified Water BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

36 months (3 Years)

6.4 Special Precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and Content of container

15g printed Lami tube. Single 15g filled tube packed in carton along with pack insert. 30g printed Lami tube. Single 30g filled tube packed in carton along with pack insert.

6.6 Special precautions for disposal and other handling

Patients should be advised to wash their hands after applying Clobetasol propionate.

7. Marketing Authorization Holder

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8. Marketing Authorization Number

H2014/CTD664/221

9. Date of first authorization/renewal of the authorization

29 MAY, 2014

10. Date of revision of the text

12 JUNE, 2026