SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

PLOBET CREAM (Clobetasol Propionate Cream USP)

2. Qualitative and quantitative composition

Clobetasol Propionate USP.....0.05%w/w

Cream Base ..... Q.S

For the full list of excipients see section 6.1

3. Pharmaceutical form

Cream

A white to off-white soft cream.

4. Clinical particulars

Therapeutic indications

Clobetasol propionate is a very active topical corticosteroid which is of particular value when used in short courses for the treatment of more resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid lupus erythematosus, and other skin conditions which do not respond satisfactorily to less active steroids.

Posology and method of administration

Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days.

If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral, may be necessary.

Repeated short courses of Plobet Cream may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of Plobet Cream can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

For topical administration.

Contraindications

• Rosacea
• Acne vulgaris
• Perioral dermatitis
• Perianal and genital pruritus
• Primary cutaneous viral infections (e.g. herpes simplex, chickenpox)
• Hypersensitivity to the preparation
• The use of Plobet Cream skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo); or dermatoses in children under one year of age, including dermatitis and napkin eruptions.

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. If Plobet Cream is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing.

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

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 Plobet Cream does enter the eye, the affected eye should be bathed in copious amounts of water.

Topical steroids 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.

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.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to

rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

Plobet Cream Cream contains cetostearyl alcohol which can cause local skin reactions (e.g. contact dermatitis), propylene glycol which may cause skin irritation and chlorocresol which may cause allergic reactions.

Interaction with other medicinal products and other forms of interaction

None reported.

Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to humans has not been established, therefore, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

The safe use of clobetasol propionate during lactation has not been established.

Effects on ability to drive and use machines

Plobet Cream is not expected to have any effects.

Undesirable effects

The following adverse reactions have been identified during post-approval use of clobetasol propionate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The frequency of these adverse events has therefore been classified as “unknown”.

Immune system disorders

Hypersensitivity

• Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the condition under treatment.

• If signs of hypersensitivity appear, application should be stopped immediately.

Endocrine disorders

Features of Cushing's syndrome

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

• Provided the weekly dosage is less than 50g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.

Vascular disorders

Dilatation of the superficial blood vessels

• Prolonged and intensive treatment with highly-active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or when skin folds are involved.

Skin and subcutaneous tissue disorders

Local skin burning, local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, pustular psoriasis.

• Prolonged and intensive treatment with highly-active corticosteroid preparations may cause local atrophic changes, such as thinning and striae.

• Treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.

5. Pharmacological properties

Pharmacodynamic properties

Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

Pharmacokinetic properties

Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased.

Mean peak plasma clobetasol propionate concentrations of 0.63 ng/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 0.05% ointment to normal individuals with healthy skin. Following the application of a second dose of 30 g clobetasol propionate cream 0.05% mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application. In a separate study, mean peak plasma concentrations of approximately 2.3 ng/ml and 4.6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0.05% ointment.

Following percutaneous absorption of clobetasol propionate, the drug probably follows the metabolic pathway of systemically administered corticosteroids, i.e. metabolised primarily by the liver and then excreted by the kidneys. However, systemic metabolism of clobetasol has never been fully characterised or quantified.

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

List of excipients

Cetomacrogol 1000 INH

Cetostearyl Alcohol BP

White Soft Paraffin BP

Sodium Acid Phosphate BP

Disodium Hydrogen Phosphate BP

Benzyl Alcohol BP

Propylene Glycol BP

Liquid Paraffin (Heavy) BP

Perfume INH

Purified Water BP

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life

36 months.

Special precautions for storage

Store at a temperature not exceeding 30°C. Do not freeze. Protect from light.
Keep out of reach of children.

Nature and contents of container Lami tube closed with a polypropylene cap. Pack sizes: 30g .

Special precautions for disposal and other handling

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

7. Marketing authorisation holder

KREMOINT PHARMA PVT. LTD.
Plant: B-8, Additional Ambernath,
M.I.D.C., Ambernath (East),
Dist. Thane – 421 506.

8. Marketing authorisation number(s)

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9. Date of first authorisation/renewal of the authorisation

Approval Date: 29.09.2020

10. Date of revision of the text

Revision of Text : 29.09.2025