

Dermova

Clobetasol Propionate BP 0.05% W/W

COMPOSITION

Dermova Cream: Each gram of cream contains Clobetasol Propionate BP 0.5 mg.

Dermova Ointment: Each gram of ointment contains Clobetasol Propionate BP 0.5 mg.

PHARMACOLOGY

Clobetasol Propionate is a very potent topical corticosteroid. It has anti-inflammatory, antipruritic and vasoconstrictive properties. It shows anti-inflammatory activity via multiple mechanisms to inhibit late phase allergic reactions. It decreases the density of mast cells, chemotaxis and activation of eosinophils. It also reduces cytokine production and inhibits the metabolism of arachidonic acid.

INDICATION

Clobetasol Propionate is indicated for adults, elderly and children over 1 year in following dermatoses.

- Psoriasis (excluding widespread plaque psoriasis)
- Recalcitrant dermatoses
- Lichen planus
- Discoid lupus erythematosus
- Other skin conditions which do not respond satisfactorily to less potent steroids

DOSAGE AND ADMINISTRATION

Route of administration: Cutaneous

Creams are especially appropriate for moist or weeping surfaces.

Ointments are especially appropriate for dry, lichenified or scaly lesions.

Adults, elderly and children over 1 year:

Apply a thin layer of Clobetasol Propionate Cream or Ointment to the affected skin areas twice daily and rub in gently and completely.

Repeated short courses of Clobetasol Propionate may be used to control exacerbations. In more resistant lesions, especially where there is hyperkeratosis, the effect of Clobetasol Propionate 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.

Clobetasol Propionate is super-high potency topical corticosteroids; therefore, treatment should be limited to 2 consecutive weeks. The maximum weekly dose should not be exceeded 50 gm/week.

In case of children, courses should be limited if possible to five days and reviewed weekly.

CONTRAINDICATION

It is contraindicated in patient with hypersensitivity to any component of the preparation. It should not be used in rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, pruritus without inflammation, untreated cutaneous infections.

WARNING AND PRECAUTION

In case of using occlusive dressings, the skin should be cleansed before a fresh dressing is applied. Topical corticosteroids should be used with caution in psoriasis as rebound relapses, and development of local or systemic toxicity due to impaired barrier function of the skin may occur. If used on the face, treatment should be limited to 5 days. When Clobetasol Propionate used on eyelids, care should be taken to avoid the eyes as cataract and glaucoma might result from repeated exposure.

SIDE EFFECT

The most reported side effects are burning and stinging sensation. Less frequent adverse reactions are itching, skin atrophy, cracking and fissuring of the skin. Cushing syndrome has been reported in infants and adults as a result of prolonged use of topical Clobetasol Propionate formulations.

USE IN PREGNANCY AND LACTATION

There are limited data from the use of Clobetasol Propionate Cream or Ointment in pregnant women. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established. However, the administration of Clobetasol Propionate during pregnancy and lactation should only be considered if the expected benefit to the mother outweighs the possible risks of treatment.

It is unknown whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Clobetasol Propionate is administered to a nursing woman.

USE IN CHILDREN & ADOLESCENT

In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur. Children are more susceptible to the use of topical corticosteroids which develops atrophic changes.

DRUG INTERACTION

Co-administered drugs that can inhibit CYP3A4 (eg Ritonavir, Itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure.

OVERDOSE

Acute overdosage is very unlikely to occur, however, in the case of chronic over-dosage or misuse the features of hypercortisolism may occur and in this situation topical steroid should be discontinued.

STORAGE CONDITION

Keep below 30°C temperature, protected from light. Do not freeze. Keep out of the reach of children.

HOW SUPPLIED

Dermova Cream: Each box contains a tube of 10 gm Dermova cream.

Dermova Ointment: Each box contains a tube of 10 gm Dermova ointment.