

Dermovate Safety Information (1/2)¹

Indication:

Clobetasol is a very potent topical corticosteroid indicated for adults, elderly and children over 1 year for the short term treatment only of more resistant inflammatory and pruritic manifestations of steroid responsive dermatoses unresponsive to less potent corticosteroids.

These include the following:

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

Scalp application: It is indicated for use in steroid responsive dermatoses of the scalp such as: psoriasis, recalcitrant dermatoses.

Dosage and administration:

Cream and ointment:

Adults, Elderly and Children over 1 year: Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day until improvement occurs (in the more responsive conditions this may be within a few days), then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient.

Repeated short courses of clobetasol propionate may be used to control exacerbations.

Recalcitrant dermatoses: Patients who frequently relapse - Once an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing (once daily, twice weekly, without occlusion) may be considered. This has been shown to be helpful in reducing the frequency of relapse.

Scalp application:

Adults, Elderly and Children over 1 year: A small quantity of clobetasol should be applied to the scalp night and morning until improvement is noticeable. It may then be possible to sustain improvement by applying once a day, or less frequently.

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Contraindications:

- Cream and ointment:
 - Hypersensitivity to the active substance or any of the excipients
 - The following conditions should not be treated with Dermovate: Untreated cutaneous infections, rosacea, acne vulgaris, pruritus without inflammation, perianal and genital pruritus, perioral dermatitis.
 - Clobetasol is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions
- Scalp Application:
 - Infections of the scalp.
 - Hypersensitivity to the active substance or any of the
 - Dermatoses in children under one year of age, including dermatitis.

Warnings and precautions:

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids.

Children are more susceptible to develop atrophic changes with the use of topical corticosteroids.

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Application to the face is undesirable as this area is more susceptible to atrophic changes. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure.

Visual disturbance has been reported with systemic and topical corticosteroid use.

Clobetasol contains paraffin. Instruct patients not to smoke or go near naked flames due to the risk of severe burns.

Adverse drug reactions:

- Common ($\geq 1/100$ and $< 1/10$): Pruritus, local skin burning /skin pain