**Indications**

For adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive 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:** Topical

Ointment is especially appropriate for dry, lichenified or scaly lesions while cream is for moist or weeping surfaces.

**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 for up to 4 weeks until improvement occurs, 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 may be used to control exacerbations. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion. If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated. The maximum weekly dose should not exceed 50gms/week.

**Atopic dermatitis (eczema)**

Application should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy. Rebound of pre-existing dermatoses can occur with abrupt discontinuation.

**Recalcitrant dermatoses**

**Patients who frequently relapse:** Once an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing may be considered. Application should be continued to all previously affected sites. Treatment should be combined with routine daily use of emollients.

**Children:** Contraindicated in children under one year of age. Care should be taken when using to ensure the amount applied is the minimum that provides therapeutic benefit.

**Elderly:** Due to greater frequency of decreased hepatic or renal function in the elderly which may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

**Renal / Hepatic Impairment:** In case of systemic absorption, metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

**Contraindications**

Contraindicated in patients with untreated cutaneous infections, rosacea, acne vulgaris, pruritus without inflammation, Perianal and genital pruritus, perioral dermatitis, children under one year of age with dermatoses.

**Warnings and Precautions**

Caution in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation. Manifestations of hypercortisolism and reversible HPA axis suppression can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency.

**Children:**

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.

**Infection risk with occlusion:**

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

**Use in psoriasis:** Topical corticosteroids should be used with caution in psoriasis as rebound relapses and careful patient supervision is important.

**Concomitant infection:** 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 administration of appropriate antimicrobial therapy.
Chronic leg ulcers: Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Application to the face is undesirable as this area is more susceptible to atrophic changes.

Application 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.

Effects on Ability to Drive and Use Machines
No adverse effects on the ability to drive or operate machinery have been identified.

DRUG INTERACTIONS
Co-administered drugs that can inhibit CYP3A4 have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure.

PREGNANCY AND LACTATION

Fertility: There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

Pregnancy: There are limited data from the use of Clobetasol propionate (Dermovate®) in pregnant women.

Lactation: The safe use of topical corticosteroids during lactation has not been established.

ADVERSE EFFECTS

Common Pruritus, local skin burning /skin pain
Uncommon Skin atrophy*, striae*, telangiectasias*
Very rare Opportunistic infection, Local Hypersensitivity, Hypothalamic-pituitary adrenal (HPA) axis suppression: Cushingoid features, delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis , Skin thinning*, skin wrinkling*, skin dryness*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis/dermatitis, pustular psoriasis, erythema, rash, urticaria, Application site irritation/pain

OVERDOSAGE AND TREATMENT

Symptoms and signs: In the case of chronic overdosage or misuse the features of hypercortisolism may occur.

Treatment: In the event of overdose, Clobetasol propionate (Dermovate®) should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid.

STORAGE CONDITION: Store at temperatures not exceeding 30°C.

INSTRUCTIONS FOR USE AND HANDLING:
There are no special requirements for use or handling of this product.

Full prescribing information available upon request

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GlaxoSmithKline

Imported by:
GlaxoSmithKline Philippines Inc
2266 Chino Roces Avenue, City of Makati
Tel. 892-0761

Mfd. By:
Glaxo Operations UK Ltd.
Barnard Castle, UK