# Dermex® S

Clobetasol Propionate BP & Salicylic Acid BP

**Description: Dermex® S** Ointment contains the active compound Clobetasol Propionate, a synthetic corticosteroid and Salicylic Acid, a keratolytic agent for topical dermatologic use. Clobetasol is an analog of prednisolone having a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity. Salicylic Acid is a keratolytic and antiseptic agent.

**Mode of action:** Clobetasol Propionate is a corticosteroids which decreases inflammation by preventing the release of prostaglandin & leukotriens and inhibiting macrophage accumulation in inflamed areas. Salicylic Acid softens and destroys the stratum corneum by increasing endogenous hydration. It also possesses weak antifungal and antibacterial activity.

**Pharmacokinetics:** Topical corticosteroids can be absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. It is metabolized, primarily in the liver, and then excreted by the kidneys. Clobetasol Propionate and its metabolites are also excreted into the bile. Salicylic Acid is well absorbed into oral mucosa.

**Composition: Dermex® S Ointment:** Each gram ointment contains Clobetasol Propionate BP 0.50 mg & Salicylic Acid BP 30 mg.

**Indications: Dermex® S** ointment is indicated for the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses such as psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

**Dosage & administration:** Apply a thin layer of **Dermex® S** ointment to the affected skin areas twice daily and rub gently and completely. For some patients, adequate maintenance therapy may be achieved with less frequent application. As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. It should not be used with occlusive dressings. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g/week because of the potential for the drug to suppress the hypothalamic pituitary adrenal (HPA) axis. Use in pediatric patients under 12 years of age is not recommended.

**Contraindications:** This ointment is contraindicated in those patients with a history of sensitivity reactions to any of its active ingredients.

**Side effects:** The most frequent adverse reactions reported for Clobetasol Propionate ointment were burning, irritation, itching and stinging sensation. Less frequent adverse reactions were erythema & telangiectasia.

**Use in pregnancy & lactation:** Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Precautions:** The ointment should not be used on the face, groin or axillae. This ointment is not for ophthalmic use. Manifestations of cushing syndrome, hyperglycemia and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy. If irritation or sensitization develops with the use of this ointment, treatment should be discontinued and appropriate therapy instituted.

**Drug interactions:** There has been no report of interaction with Clobetasol Propionate ointment and cream. There are no known interactions of Salicylic Acid when used as indicated. However, topical Salicylic Acid may increase the absorption of other topically applied medicines. Concomitant use of Salicylic Acid Ointment and other topical medicines on the same area of skin should therefore be avoided.

**Over dosage**

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 discontinued gradually. Most adult deaths occur in patients whose concentrations exceed 700 ml/L. Single doses less than 100 mg/kg are unlikely to cause serious poisoning.

**Storage:** Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

**Packaging: Dermex® S 30 gm Ointment:** Each carton contains a tube of 30 gm ointment.

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