Dermex®

Clobetasol Propionate

Description: Clobetasol Propionate (**Dermex®**) ointment and cream is a synthetic corticosteriod, for topical dermatologic use.

Mode of action: Like other topical corticosteroids, clobetasol propionate has anti-inflammatory, antipruritic and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Pharmacokinetics: Clobetasol propionate is absorbed through the skin in varying proportions of the applied dose depending upon the severity of the damage to the stratum corneum barrier that has resulted from the skin disease being treated.

Composition: Dermex® Cream: Each gm cream contains Clobetasol Propionate BP 0.5 mg.
Dermex® Ointment: Each gm ointment contains Clobetasol Propionate BP 0.5 mg.

Indications: Initial control of all forms of hyperacute eczema in all age groups (in children for no longer than a few days); chronic hyperkeratotic eczema of the hands and feet and patches of chronic lichen simplex; chronic hyperkeratotic psoriasis of any area of the body; severe acute photosensitivity; hypertrophic lichen planus; localized bullous disorders; keloid scarring; pretibial myxoedema; vitiligo; suppression of reaction after cryotherapy.

Dosage & 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. If a longer course is necessary, it is recommended that treatment should not be continued for more than four weeks without the patient's condition being observed. Repeated short courses of clobetasol propionate 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 antiinflammatory effect of clobetasol propionate can be enhanced, if necessary, by occluding the treatment area with polythene film. Only overnight occlusion is usually adequate to bring about a satisfactory response. Thereafter, improvement can usually be maintained by application without occlusion.
Clobetasol propionate may be used in children in appropriate doses, but large quantities for prolonged periods should be avoided. The drug is contraindicated in children less than 1 year old.

Contraindications: Cutaneous infections such as impetigo; tinea corporis and herpes simplex; Infestations such as scabies; Neonates (Children less than one year old); Acne vulgaris; Rosacea; Gravitational ulceration.

Side effects: Provided the weekly dosage is less than 50 gm in adults, any pituitary-adrenal suppression is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. Use of occlusive dressings increases the absorption of topical corticosteroids. Prolonged and intensive treatment with a highly active corticosteroid preparation may cause atrophic changes, such as thinning, striae and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or where skin folds are involved.

Use in pregnancy & lactation: This drug should be avoided in pregnant women. Mothers using large amounts of the drug should be aware of potential excretion in milk.

Precautions: Long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion. If clobetasol propionate 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 clobetasol propionate 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.

Drug interactions: No hazardous interactions have been reported with use of Clobetasol Propionate.

Overdosage: 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.

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

Packaging: Dermex® Cream: Each carton contains a tube having 20 gm cream.
Dermex® Ointment: Each carton contains a tube having 30 gm ointment.

Opsonin Pharma
Ideas for healthcare

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