

DERMACORT

CLOBETASOL PROPIONATE USP

Compositions:

White non-staining water miscible cream/Ointment containing Clobetasol Propionate USP 0.05% w/w.

Pharmacology:

Clobetasol Propionate is a corticosteroid used typically for its glucocorticoid activity in the treatment of various skin diseases. It has potent anti-inflammatory and immunosuppressive effects.

Dosage And Administration:

Apply Dermacort Cream/Ointment sparingly to the affected areas once or twice daily until improvement occurs. As with other highly active topical steroid preparation, 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 Dermacort may be used to control exacerbation. In very resistant lesions especially where there is hyperkeratosis, the anti-inflammatory effect of Dermacort can be enhanced 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.

Contraindications:

It is contraindicated in: Cutaneous infections such as impetigo, tinea corporis and herpes simplex, Infestation such as scabies, Neonates (children less than one year old.), Acne vulgaris, Rosacea, Gravitational ulceration.

Warning And Precaution:

Long-term continuous use of Clobetasol cream/ointment should be avoided, particularly in infants and children, in whom adrenal suppression occurs readily. If required for use in children, it is recommended that the treatment should be reviewed weekly. The face more than other area of the body may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating facial conditions. If applied to the eyelid, care is needed to ensure that the preparation doesn't enter the eye, as glaucoma may result. Appropriate microbial therapy should be used whenever treating inflammatory lesions, which have been infected. Any spread of infections require withdrawal of corticosteroid therapy and institution of suitable systemic chemotherapy. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied.

Side Effects:

Provided the weekly dosage is less than 50 gm in adult, 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. Prolonged and intensive treatment with a highly active corticosteroid preparation may cause atrophic changes, such as thinning and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or where skin folds are involved. Clobetasol cream/ointment is usually well tolerated but if signs of hypersensitivity appear, application should be stopped immediately.

Use in Pregnancy and Lactation:

Topical administration of corticosteroids to the pregnant animals can cause abnormalities of

fetal development. The relevance of this finding to human being has not been established. However, topical steroids shouldn't be used extensively in pregnancy, i.e. in large amount or for prolonged period.

Drug Interaction:

Co-administered drugs that can inhibit CYP3A4 (eg ritonavir and itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor

Overdosage:

Symptoms and signs Topically applied DERMOVATE may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur (see Adverse Reactions). Treatment In the event of overdose, DERMOVATE should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency

Storage:

Store in a cool (below 30°C) and dry place. Keep away from light and out of reach of children.

Packing:

Tube contains 10 gm cream/ointment.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.