Clozema®

Clobetasol Propionate

COMPOSITION:

Clozema ® Cream: Each 10 gm cream contains Clobetasol Propionate BP 5 mg.
Clozema ® Ointment: Each 10 gm ointment contains Clobetasol Propionate BP 5 mg.

PHARMACOLOGY:

Clobetasol Propionate is a highly potent topical steroid. It has both local anti inflammatory and immunosuppressive activity. When given systemically it has standard glucocorticoid activity and binds with high affinity to the glucocorticoid receptor. Clobetasol Propionate inhibits the adherence of neutrophils and monocyte-macrophages; to the capillary endothelial cells of inflammed area. Clobetasol blocks the effect of macrophage migration inhibitory factor and decreases the activation of plasminogen to plasmin.

INDICATION:

Clozema ® is indicated in:

1. Initial control of all forms of hyperacute eczema in all age groups. 2. Chronic hyperkeratotic eczema of the hands and feet and patches of chronic lichen simplex. 3. Chronic hyperkeratotic psoriasis of any area of the body. 4. Severe acute photosensitivity. 5. Acute contact Dermatitis 6. Hypertrophic lichen planus. 7. Localized bullious disorders. 8. Keloid scarring. 9. Pretibial myxedema. 10. Suppression of reaction after Cryotherapy. 11. Vitiligo.

DOSE & 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 Clozema ® 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 anti-inflammatory effect of Clozema ® can be enhanced, if necessary, by occluding the treatment area with polyethelene film. Only overnight occlusion is usually adequate to bring about a satisfactory response. Thereafter, improvement can usually be maintained by application without occlusion.

CONTRA-INDICATION:

Clobetasol Propionate is contraindicated in:

1. Cutaneous infections such as impetigo, tinea corporis and Herpes simplex 2. Infections such as scabies 3. Neonates (Children less than one year old) 4. Acne vulgaris 5. Rosacea 6. Gravitational ulceration.

WARNING & PRECAUTION:

Long term continuous therapy with Clobetasol Propionate should be avoided, particularly in infants and children, in whom adrenal suppression occurs readily. If Clobetasol Propionate is required for use in children, it is recommended that the treatment should be reviewed on weekly basis. It should be noted that the infants napkin may act as occlusive dressing. 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 which warrants use of Clobetasol Propionate and frequent observation of the patient is important.

SIDE EFFECTS:

Provided the weekly dosage is less than 50g in adults, any pituitaryadrenal suppression is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage. 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:

Clobetasol Propionate should be avoided in pregnant women. Mothers using large amounts of the drug should be aware of potential excretion in milk.

USE IN CHILDREN AND ADOLESCENTS:

Use of Clobetasol Propionate in pediatric patients is not recommended due to the potential for HPA axis suppression. Because of higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. 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. Children are more susceptible to develop atrophic changes with the use of topical corticosteroids. If it is required for use in children, it is recommended that the treatment should be limited to only a few days and reviewed weekly.

DRUG INTERACTION:

Co-administered drugs that can inhibit CYP3A4 (eg ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure.

OVERDOSE:

Acute overdose is very unlikely to occur. However, in the case of chronic overdosage or misuse, the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

STORAGE:

Store in a dry and cool place, below 30^0 C temperature and keep away from light and moisture. Keep out of the reach of children.

PACKING:

Clozema ® Cream: Each box contains 10 gm cream in a tube.
Clozema ® Ointment: Each box contains 10 gm ointment in a tube.

Manufactured by
Team Pharmaceuticals Ltd.
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