Halobet™

Halobetasol Propionate

COMPOSITION

Halobet™ 0.05% Cream: Each gm cream contains Halobetasol Propionate INN 0.5 mg.

Halobet™ 0.05% Ointment: Each gm ointment contains Halobetasol Propionate INN 0.5 mg.

PHARMACOLOGY

Like other topical corticosteroids, Halobetasol Propionate has anti-inflammatory, anti-pruritic and vasoconstrictive actions. The mechanism of the anti-inflammatory activity of the topical corticosteroids, in general, is unclear. However, corticosteroids are thought to act by the 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.

INDICATION

Halobetasol Propionate 0.05% is a super-high potent corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Treatment beyond two 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.

DOSAGE & ADMINISTRATION

Apply a thin layer of **Halobet**™ Cream or Ointment to the affected skin once or twice daily, as directed by the physician, and rub in gently and completely. Halobetasol Propionate 0.05% is a super-high potency corticosteroid; therefore, treatment should be limited to two weeks, and amounts greater than 50 g/week should not be used. 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 the diagnosis may be necessary. Halobetasol Propionate should not be used with occlusive dressings. Use in children under 12 years of age is not recommended.

CONTRAINDICATION

Halobetasol Propionate is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTION

Systemic absorption of topical corticosteroids may cause reversible Hypothalamic-Pituitary-Adrenal (HPA) axis suppression, manifestations of cushing's syndrome, hyperglycemia, and glucosuria. Patients receiving large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Safety and effectiveness of Halobetasol Propionate cream & ointment in paediatric patients have not been established. Paediatric patients are at greater risk than adults of HPA axis suppression when they are treated with topical corticosteroids.

USE IN PREGNANCY & LACTATION

Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore caution should be exercised when topical corticosteroids are administered to a nursing woman.

ADVERSE REACTION

The following adverse effects have been reported infrequently with topical corticosteroids. These reactions include burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infections, skin atrophy, striae and miliaria.

STORAGE

Store below 30° C. Do not freeze. Keep all medicines out of reach of children.

HOW SUPPLIED

Halobet™ 0.05% Cream - Each pack has a tube containing 20 gm cream.

Halobet™ 0.05% Ointment - Each pack has a tube containing 20 gm ointment.

Manufactured by

SQUARE

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH