Halocort®

Halobetasol Propionate INN 0.05% w/w

Description

Halocort® is the preparation of Halobetasol Propionate, a synthetic corticosteroid for topical dermatological use. Like other topical corticosteroids, Halobetasol Propionate has anti-inflammatory, antipruritic 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.

Indications

Halocort® is a super-high potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Dosage and administration

Apply a thin layer of Halocort® to the affected skin once or twice daily, as directed by the physician, and rub in gently and completely. Halocort® is a super-high potency topical corticosteroid; therefore, 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. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. Halocort® should not be used with occlusive dressings.

Pediatric use

Safety and effectiveness of Halocort® in pediatric patients have not been established and use in pediatric patients under 12 years is not recommended.

Geriatric use

No overall differences in safety or effectiveness were observed between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Use in pregnancy & lactation

Pregnancy

Pregnancy category is C. There are no adequate and well-controlled studies of the teratogenic potential of Halobetasol Propionate in pregnant women. Halobetasol Propionate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Caution should be exercised when topical Halobetasol Propionate is administered to a nursing woman.

Side effects

The most frequent side effects are stinging, burning or itching. Less frequently reported side effects are pustulation, erythema, skin atrophy, leukoderma, acne, vesicles, secondary infection, telangiectasia, urticaria, dry skin, miliaria, paresthesia, and rash.

Precautions

If irritation develops, Halobetasol Propionate should discontinued and appropriate therapy instituted. Halobetasol Propionate produced HPA axis suppression when used in divided doses at 7 g per day for one week in patients with psoriasis. These effects were reversible upon discontinuation of treatment. Halobetasol Propionate should not be used in the treatment of rosacea or perioral dermatitis, and it should not be used on the face, groin, or in the axillae.

Contraindications

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

Pharmaceutical precautions

Store in a cool & dry place protected from light. Keep all medicines away from the reach of children.

Presentation

Halocort® 0.05% Cream: Each gram of Halocort® cream contains 0.5mg Halobetasol Propionate INN.

Halocort® 0.05% Ointment: Each gram of Halocort® ointment contains 0.5mg Halobetasol Propionate INN.

Package quantities

Halocort® 0.05 % Cream: Tube of 10g.

Halocort® 0.05 % Ointment: Tube of 10g.

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