HALONOVA

For the use of Dermatologists or a Hospital or a Laboratory Only

Abbreviated Prescribing information for HALONOVA (Halobetasol Propionate Cream 0.05 % w/w) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Halobetasol propionate is an ultra-high-potency corticosteroid for topical dermatological use.

INDICATION: Halobetasol propionate cream is an ultra 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 HALONOVA to the affected skin once or twice daily, as directed by your physician, and rub in gently and completely. Treatment should be limited to 2 weeks, and amounts greater than 50 g/week should not be used. Therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. Should not be used with occlusive dressings.

CONTRAINDICATION: Known hypersensitivity to any component of preparation. In patient(s) having viral diseases of the skin including herpes simplex, vaccinia and varicella.

WARNINGS & PRECAUTIONS: Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression after withdrawal, Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients, if systemic absorption occurs. Patients receiving super potent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression. 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 corticosteroid. Use in children under 12 years of age is not recommended. For external use only. Avoid contact with the eyes. Should not be used in the treatment of rosacea or perioral dermatitis, not be used on the face, groin, or in the axillae. Use with cautions in patients with stasis dermatitis and other skin diseases associated with impaired circulation, hypersensitive patients and patients with glaucoma.

ADVERSE REACTIONS: Frequently reported: Stinging, burning or itching. Less frequently reported: dry skin, erythema, skin atrophy, leukoderma, vesicles, rash, pustulation, leukoderma, acene, itching, secondary infection, telangiectasia, urticara, miliaria, paresthesia. Less frequent: folliculitis, hypertrichosis, acneiform eruptions, hypo- pigmentation, perioral dermatitis, allergic contact dermatitis.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA

IN/HALONOVA/FEB 2015/01/AbPI

(Additional information is available on request)