

HALONOVA

For the use of a Registered Medical Practitioner 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:

MECHANISM OF ACTION: 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 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 A2.

INDICATIONS: Halobetasol propionate cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

DOSAGE AND ADMINISTRATION: Apply a thin layer of Halobetasol Propionate Cream to the affected skin once or twice daily, as directed by your physician, and rub in gently and completely. Halobetasol Propionate Cream is a super-high potency topical corticosteroid; therefore, treatment should be limited to two weeks, and amounts greater than 50 g/week should not be used. 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. Halobetasol Propionate Cream should not be used with occlusive dressings. For topical use only.

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

WARNINGS & PRECAUTIONS: Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. Halobetasol Propionate Cream produced HPA axis suppression when used in divided doses at 7 grams per day for one week in patients with psoriasis. These effects were reversible upon discontinuation of treatment. 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. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. If irritation develops, Halobetasol Propionate Cream should be discontinued, and appropriate therapy instituted. If a favourable response does not occur promptly, use of Halobetasol Propionate Cream should be discontinued until the infection has been adequately controlled. Halobetasol Propionate Cream 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.

DRUG INTERACTIONS: None known.

ADVERSE REACTIONS: In controlled clinical trials, the most frequent adverse events reported for Halobetasol Propionate Cream included stinging, burning or itching in 4.4% of the patients. Less frequently reported adverse reactions were dry skin, erythema, skin atrophy, leukoderma, vesicles and rash. The following additional local adverse reactions are reported infrequently with topical corticosteroids, and they may occur more frequently with high potency corticosteroids, such as Halobetasol Propionate Cream. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

MARKETED BY:



Torrent Pharmaceuticals Limited.

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(Additional information is available on request)