

## HALONOVA-S

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

Abbreviated Prescribing information for HALONOVA-S (Halobetasol Propionate 0.05 % w/w & Salicylic Acid 3.0 % w/w Ointment) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com) ]

**PHARMACOLOGICAL PROPERTIES:** Halobetasol propionate is an ultra-high-potency corticosteroid for topical dermatological use. Salicylic Acid produce desquamation of the horny layer of skin by dissolution of intercellular cement substance.

**INDICATION:** Indicated for topical treatment of chronic plaque psoriasis.

**DOSAGE AND ADMINISTRATION:** Apply a thin layer to the affected skin areas once or twice daily as directed by your physician and rub in gently and completely. For some patients, adequate maintenance therapy may be achieved with less frequent application. Ointment should not be used with occlusive dressings. The ointment is for external use only and avoid contact with eyes and other mucous membranes.

**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. Risk of salicylism (identified by nausea, vomiting, dizziness, loss of hearing, tinnitus, lethargy, hyperpnea, diarrhea, and psychic disturbances) on prolonged use over large areas, especially in children, patients with renal or hepatic impairment or on concomitant use of salicylate containing drugs such as aspirin which may contribute to elevated serum salicylate levels. In such case discontinue therapy, administer fluids (oral or IV sodium bicarbonate) to promote urinary excretion and apply occlusive dressings, clothing or petrolatum-based ointments to prevent excessive systemic exposure to salicylic acid. Potential risk of Reye's syndrome in children and teenagers with varicella or influenza.

**DRUG INTERACTIONS:** interacts with sulfonyleureas, methotrexate, oral anticoagulants, corticosteroids, heparin, pyrazinamide, probenemide, sulfapyrazone and phenylbutazone.

**ADVERSE REACTIONS:** Stinging, burning or itching, dry skin, excessive erythema, skin atrophy, leukoderma, vesicles, rash, pustulation, leukoderma, acne, itching, secondary infection, telangiectasia, urticaria, miliaria, paresthesia, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis and scaling conceivably could result from use on open skin lesions.

### MARKETED BY:



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(Additional information is available on request)