# **Betasalic** Ointment

[Betamethasone/Salicylic Acid] FOR DERMATCLOGIC USE ONLY



Betasalic ointment provides in each gram: Betamethasone as dipropionate BP 0.5 mg and Salicylic acid SP 30 mg. Salicylic acid is a keratolytic and antiseptic

Betamethasone dipropionate a synthetic corticosteroid has anti-inflammatory. anti pruritic and vasoconstrictiva action. Topical Sallcylic acid has keratolytic properties as well as bacteriostatic and fungicidal actions. Betasalic cimment demonstrates these actions in a sustained manner thereby permitting twice a day application.

## INDICATIONS:

Betasalic ointment is indicated for the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses such as psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, edzema (including nummular edzema, hand edzema, edzematius dermatius), dyshidrosis (pompholyx, sebormeic dermatius of the scalp, ichthyosis vulgeris and other ichthyotic conditions.

## DOSAGE AND ADMINISTRATION:

A thin film of Betasalic ointment should be applied to cover completely the affected area, twice daily, in the morning and at night. For some patients, adequate maintenance therapy may be achieved with less frequent applications.

## ADVERSE REACTIONS:

Adverse reactions that have been reported with the use of topical corticosteroids include: burning, fiching, irritation, dryness, folloculitis, hypertrichosis, scneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis. The following may occur more frequently with the use of occlusive dressings: maceration of the skin secondary infection, skin atrophy, striae and miliaria. Salicylic acid preparations may cause dermatitis.

## CONTRAINDICATIONS:

Betasalic ointment is contraindicated in those patients with a history of sensitivity reactions to any of its components.

If irritation or sensitization develops with use of Betasalic ointment, treatment should be discontinued. In the presence of an infection, appropriate therapy is indicated. Any of the side effect that is reported following systemic use of corticosteroids including adrenal suppression, may also occur with topical corticosteroids including adrenal suppression. corticosteroids, especially in infants and children. Systemic absorption of topical curlicosteroids or salicylic acid will be increased if extensive body surface areas are treated or if the occlusive technique is used suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children, if excessive dryness or increased skin irritation develops discontinue use of this preparation. Betasalic continuer is not for ophthalmic use.

Avoid contact with eyes and mucous membranes. Pediatric patients may demonstrate greater susceptibility to topical corticosteroids-induced hypothalamic-pituitary adrenal (HPA) axis suppression and to exogenous corticosteroids effects than mature patient because of greater absorption due to a large skin surface area to body weight ratio HPA axis suppression. Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hyportension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACT stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches bilateral papilledema.

Since safety of topical corticosteroid use in pregnant women has not been established drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to fetus. Drugs of this class should not be used extensively in large amounts or for prolonged period of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### OVER DOSAGE:

Excessive or protonged use of topical conticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency and produce manifestrations of hyperconticism, including Cushing's disease. Excessive or prologned use of topical preparations containing salicylic acid may cause symptoms of salicylism.

### TREATMENT:

Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary, in case of chronic toxicity slow withdrawal of conicosteroids is advised.

Treatment of salicylism is symptomatic. Measures should be taken to rid the body rapidly of salicylate administer oral sodium bicarbonate to alkalinize the urine and force diuresis.

## INSTRUCTIONS:

Protect from light & heat. Store below 30°C. Replace cap securely after use, Keep out of the reach of children. Use as directed by the physician.

### HOW SUPPLIED:

Betasailc ointment is available in 15gm aluminium tube.

بدلیات: روش اورگری سے ایما کیں۔ ۲۰۰ فرگری سنٹی کرتے ہے کم دردیا حمارت پر دکھی۔ پیمان کا بی سے دورزیکس۔ داکم کی بدایت کے مطابق استان کرتے۔

04008N-02

