

# BETACYLIC OINTMENT

## Ingredient(s):

Each gram contains :

Betamethasone ..... 0.5mg (0.05%w/w)  
(eq. to Betamethasone Dipropionate 0.643mg)

Salicylic Acid ..... 30mg (3.0%w/w)

## Inactive ingredients:

Mineral Oil, White Petrolatum

## Pharmacodynamics:

Betacylic Ointment contain the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids, and salicylic acid which has keratolytic properties.

Salicylic acid is applied topically in the treatment of hyperkeratotic and scaling conditions where its keratolytic action facilitates penetration of the corticosteroid. In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

## Pharmacokinetics:

Salicylic acid exerts only local action after topical application.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolized primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

## Indication(s):

Relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses eg., psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

## Dosage & Administration:

Apply a thin film to completely cover the affected area, twice daily, in the morning and at night. For some patients, adequate maintenance therapy may be achieved with less frequent application.

To be applied topically.

## Contraindication(s):

Patients with a history of sensitivity reactions to any of the components of this product.

## Warning and Precautions:

1. Treatment should be discontinued if irritation or sensitization develops with the use of this product.
2. In the presence of an infection, appropriate therapy is indicated.
3. Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.
4. Systemic absorption of topical corticosteroids 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.
5. If excessive dryness or increased skin irritation develops, discontinue use of this product.
6. This product is not for ophthalmic use. Avoid contact with eyes and mucous membranes.

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260mm  
(±2mm)

7. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

**Pediatric Use:**

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients 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 hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

**Interaction with Other Medicaments:**

Not known

**Pregnancy and Lactation:**

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 the fetus and should not be used extensively in large amounts or for prolonged period.

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.

**Side Effects:**

1. Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.
2. The following may occur more frequently with the use of occlusive dressings: Maceration of the skin, secondary infection, skin atrophy, striae and miliaria.
3. Salicylic acid preparations may cause dermatitis.
4. Eye disorders: Vision, blurred.

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**Symptoms and Treatment of Overdose:**

**Symptoms:** Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease. Excessive or prolonged use of topical preparations containing salicylic acid may cause symptoms of salicylism.

**Treatment:** Appropriate symptomatic treatment is indicated. Acute hypercorticism symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroid 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 forced diuresis.

**Storage condition:**

Keep in a tight container. Store below 30°C, protect from light and moisture.

**Shelf Life:**

3 Years from the date of manufacture.

**Product Description and Packing (s):**

Slight transparent, off white color ointment.  
Aluminium tube of 10g.



Manufacturer and Product Registration Holder:  
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