

Package Insert

Epiklin™
Skin Ointment

Betamethasone Dipropionate and Salicylic Acid Ointment

Composition:
Betamethasone Dipropionate USP 0.64mg
Salicylic Acid USP 30.00mg
In an ointment base q.s. to make 1g

Product Description
A smooth uniform off-white ointment, free from foreign matter.

Pharmacodynamics
EPIKLIN SKIN 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
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, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

Recommended Dose
Once to twice daily. In most cases a thin film should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application. The maximum weekly dose should not exceed 60g.

Mode Of Administration
Topical

Contraindication
Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the EPIKLIN SKIN OINTMENT contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, varicella, varicella. EPIKLIN SKIN OINTMENT

should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy .

Warning and Precautions
Occlusion must not be used, since under these circumstances the keratolytic action of salicylic acid may lead to enhanced absorption of the steroid. Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. Long term continuous therapy should be avoided in all patients irrespective of age. Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important. It is dangerous if EPIKLIN SKIN OINTMENT come into contact with the eyes. Avoid contact with the eyes and mucous membranes. The systemic absorption of betamethasone dipropionate and salicylic acid may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.

Interactions With Other Medicaments
No known data.

Pregnancy and Lactation
Safety of its use during pregnancy and lactation has not been established. Thus it should be used only if the potential benefit justifies the potential risk to the foetus or nursing infant

Side Effects
EPIKLIN SKIN OINTMENT are generally well tolerated and side-effects are rare. Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face. In addition, prolonged use of salicylic acid preparations may cause dermatitis.

Symptoms And Treatment of Overdose
Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic treatment is indicated. With topical preparations containing salicylic acid excessive prolonged use may result in symptoms of salicylism. Treatment is symptomatic. The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

Storage Condition
Store at temperature below 30°C and Do not freeze.

Shelf Life
36 months from the date of manufacture.

Presentation
the pack of aluminium tube 15gm.

Date of revision – September, 2019


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PRODUCT NAME	: Epiklin Ointment	COUNTRY : Malaysia	LOCATION : Pithampur	Supersedes A/W No.: ZE0EXX2-MY		
ITEM / PACK	: Insert	NO. OF COLORS: 1	REMARK :			
DESIGN STYLE	: -	PANTONE SHADE NOS.:	SUBSTRATE :			
CODE	: xxxxxxx-5253		Activities	Department	Name	Signature
DIMENSIONS (MM)	: 130 L x 120 W mm	 Black C	Prepared By	Pkg.Dev		
ART WORK SIZE	: S/S		Reviewed By	Pkg.Dev		
DATE	: 18-09-2019		Approved By	Quality		

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.