BETAPROSALIC OINTMENT

COMPOSITION
Each gram of the ointment contain Betamethasone dipropionate (Micronised) equivalent to 0.5 mg of Betamethasone and Salicylic acid 30mg

PRODUCT DESCRIPTION
A white to pale yellow, smooth ointment.

PHARMACODYNAMICS
Betaprosalic preparations 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 metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

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

RECOMMENDED DOSAGE
Apply a thin film to cover completely the affected area, twice daily, morning and evening or as directed.

ROUTE OF ADMINISTRATION
Topical Administration

CONTRAINDICATIONS
Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the Betaprosalic presentations contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vacinia, varicella. Betaprosalic should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

WARNINGS 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. If used in children or on the face courses should be limited to 5 days. 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 Betaprosalic presentations 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.

If irritation or sensitisation develops with the use of Betaprosalic Ointment treatment should be discontinued.

Any side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

If excessive dryness or increased skin irritation develops, discontinue use of this preparation.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.

Paediatric population: Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituary-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.

DRUG INTERACTION

Not known.

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. Drugs of this class should not be used extensively in large amounts or for prolonged periods 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.

ADVERSE EFFECTS

Betaprosalic skin preparations 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.

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.

The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

Vision blurred has been reported with corticosteroid use (frequency not known).

In addition, prolonged use of salicylic acid preparations may cause dermatitis.

OVERDOSE AND TREATMENT

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

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 corticosteroids is advised.

With topical preparations containing salicylic acid excessive prolonged use may result in symptoms of salicyclism. Treatment is symptomatic. Measures should be taken to rid the body rapidly of salicylate. Administer oral sodium bicarbonate to alkalinise the urine and force diuresis.

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 CONDITIONS
Store below 30°C.
For external use only
Protect from light and freezing
Keep container tightly closed

PRESENTATION
Aluminium tube of 10g and 15g

MANUFACTURED BY
Noripharma Sdn Bhd.,
Lot 5030 Jalan Teratai,
5½ Mile Off Jalan Meru,
41050 Klang, Selangor.

DATE OF REVISION
7th May 2019