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BEPROSALIC OINTMENT

NAME AND STRENGTH OF ACTIVE SUBSTANCES : Betamethasone dipropionate 0.064% w/w (equiv. to Betamethasone 0.05% w/w) and Salicylic acid 3% w/w.

PRODUCT DESCRIPTION : A white ointment.
Other ingredients: White soft paraffin and Liquid paraffin.

PHARMACODYNAMICS : Betamethasone dipropionate is a topically active fluorinated corticosteroid which has anti-inflammatory, anti-pruritic and vasoconstrictive actions. Salicylic acid has keratolytic properties, as well as bacteriostatic and fungicidal actions.

PHARMACOKINETICS : When administered topically , particularly under occlusive dressing or when the skin is broken, sufficient corticosteroid may be absorbed to give systemic effects. Corticosteroids are extensively bound to plasma proteins. Only unbound corticosteroid has pharmacological effects or is metabolized. They are metabolized mainly in the liver, also in the kidney and are excreted in the urine. When salicylic acid is administered topically to large areas of the body, it may cause symptoms of acute systemic salicylate poisoning.

INDICATIONS : 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.

CONTRAINDICATIONS : Hypersensitivity to Betamethasone dipropionate, other corticosteroids, Salicylic acid, or other salicylates, or any component in the base. Topical corticosteroids are contraindicated in most viral infections of the skin and also tuberculosis and acne rosacea.

DRUG INTERACTIONS : Not known.

SIDE EFFECTS/ADVERSE REACTIONS : Reported local adverse reactions associated with corticosteroids are burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids. Salicylic acid preparations may cause dermatitis.

WARNINGS AND PRECAUTIONS : Discontinue use if irritation, sensitivity, excessive dryness or other reactions develop. In the presence of infection appropriate treatment should be given. Corticosteroids applied topically can be absorbed in sufficient amount to produce systemic effects like adrenal suppression, manifestation of Cushing's syndrome, hyperglycaemia and glucosuria in some patients, particularly in infants and children. 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. Salicylic acid in preparations applied to the skin can also be absorbed in sufficient amounts to produce salicylism. Therefore suitable precautions must be taken with Beprosalic Ointment during prolonged treatment, when treating extensive body surface areas, when using the occlusive technique and when treating children (because of a larger skin surface area to bodyweight ratio). Suitable precautions must be taken when treating stasis dermatitis and other skin diseases with impaired circulation. Discontinue use if irritation, sensitivity or other reactions develop and institute appropriate treatment. Not suitable for ophthalmic use. Do not use in or around the eyes.

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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.

OVERDOSAGE
Symptoms : Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency. Excessive prolonged use of topical preparations containing Salicylic acid may cause symptoms of salicylism.
Treatment : Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic corticosteroid toxicity, slow withdrawal of steroids is advised. Treatment of salicylism is symptomatic. Measures should be taken to rid the body of salicylate. Administer oral sodium bicarbonate to alkalinize and force diuresis.

ROUTE OF ADMINISTRATION: Topical.

RECOMMENDED DOSE : A thin film of BEPROSALIC 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 application.

PACKING : Plastic jars of 450g for export only.
Collapsible aluminium tube of 15g.
Not all pack size may be available locally.

STORAGE : Keep container well closed. Protect from light. Store below 30°C.
For external use only. Keep out of reach of children. Shelf-life: 3 years.

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