

# DIPROSALIC OINTMENT AND SCALP APPLICATION

## ABBREVIATED PRESCRIBING INFORMATION

**Uses:** Diprosalic Ointment contains Betamethasone 0.05% as dipropionate and Salicylic Acid 3%. Diprosalic Scalp Application contains Betamethasone 0.05% as dipropionate and Salicylic Acid 2% and are indicated for the treatment of hyperkeratotic and dry corticosteroid-responsive dermatoses where the cornified epithelium may resist penetration of the steroid. The salicylic acid constituent of Diprosalic preparations, as a result of its descaling action, allows access of the dermis more rapidly than by applying steroid alone.

**Dosage:** A thin film should be applied once or twice daily, with review after 2 weeks. Maximum weekly dose should not exceed 60g.

**Contraindications, Precautions and Warnings:** *Contraindications:* rosacea, acne, perioral dermatitis, perianal and genital pruritis. Hypersensitivity to ingredients. Tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. Do not use in napkin eruptions, fungal or bacterial skin infections without a suitable concomitant anti-infective therapy. *Precautions and Warnings:* Occlusion must not be used. Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion, and should be avoided in all patients. Use in children or on the face should be limited to 5 days. Use in psoriasis may result in rebound relapse due to tolerance, risk of generalised pustular psoriasis or local systemic toxicity due to impaired barrier function of skin. Careful supervision is important. Treatment of extensive body surfaces or skin folds may lead to increased systemic absorption. Discontinue use if excessive dryness, sensitisation or increased skin irritation develops. Side effects reported following systemic use of corticosteroids, including adrenal suppression, may occur with topical steroids especially in infants and children. Paediatric 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 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. 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. Suitable precautions should be taken, especially in infants and children. *Pregnancy and Lactation:* 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 foetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients. 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.

**Undesirable Effects:** Diprosalic preparations are well tolerated and side-effects are rare. Adverse reactions include burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis. Prolonged use of corticosteroids and salicylic acid may result in local atrophy of the skin, striae, superficial vascular dilation and dermatitis. Maceration of the skin, secondary infection, skin atrophy, striae and miliaria may occur more frequently with the use of occlusive dressings. The Summary of product Characteristics (SmPC) should be consulted for further details.

**Overdose:** 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: Symptomatic treatment. Acute hypercorticotoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised. Excessive prolonged use of salicylic acid can result in symptoms of salicyclism. Treatment: Symptomatic treatment. Measures should be taken to rid the body rapidly of salicylate. Administer oral sodium bicarbonate to alkalinise the urine and force diuresis. Accidental oral ingestion has little or no toxic effect due to low steroid content.

**Pack size:** Diprosalic Ointment: 30g or 100g; Diprosalic Scalp Application: 100ml. **NHS**

**Price:** Diprosalic Ointment: £3.18 (30g); £9.14 (100g); Diprosalic Scalp Application: £10.10 (100ml); **Legal Category:** POM. **Marketing Authorisation Numbers:** Diprosalic Ointment: 0201/0070; Diprosalic Scalp Application: 0201/0069.

**Marketing Authorisation Holder:** Schering-Plough Ltd, Shire Park, Welwyn Garden City, Herts, AL7 1TW.

**Please refer to the full SPC text before prescribing this product. Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) (UK). Adverse events should also be reported to Schering-Plough Drug Safety Department on +44 (0)1707 363773.**

**Date of Revision of Text:** November 2010

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