

# DIPROSONE CREAM AND OINTMENT

## **(Betamethasone Dipropionate)**

### ABBREVIATED PRODUCT INFORMATION

**Uses:** Diprosone products contain Betamethasone 0.05% as Dipropionate, a synthetic fluorinated corticosteroid. Diprosone products are active topically and produce rapid and sustained response in eczema and dermatitis including atopic eczema, photodermatitis, lichen planus, lichen simplex, prurigo nodularis, discoid lupus erythematosus, necrobiosis lipoidica, pretibial myxoedema and erythroderma. It is also effective in psoriasis of the scalp and chronic plaque psoriasis of hands and feet but not widespread plaque psoriasis. **Dosage:** Adults and Children: A thin film should be applied to cover the affected area once or twice daily. **Contraindications:** Rosacea, acne, perioral dermatitis, perianal and genital pruritis. Hypersensitivity to any of the ingredients. Presence of tuberculous or most viral lesions of skin, also napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy. **Precautions and Warnings:** Courses on the face or in children should be restricted to 5 days; long-term continuous therapy should be avoided in all patients and occlusion must not be used. 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. General: Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. If irritation develops, treatment should be discontinued and appropriate therapy instituted. Not for ophthalmic use. Paediatric Use: Paediatric patients may be more susceptible to systemic toxicity from equivalent doses; to topical corticosteroid-induced HPA axis suppression; to exogenous corticosteroid-induced HPA axis suppression; and to exogenous corticosteroid effects than adult patients because of greater absorption due to a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome and tracrancial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

**Pregnancy and Lactation:** There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

**Side Effects:** Diprosone preparations are generally well tolerated and side effects are rare. Treatment of extensive areas or skin folds for long periods or with excessive amounts may increase systemic absorption. Long term use may cause local atrophy of skin and superficial vascular dilation particularly on the face. Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria have been reported with product use. The Summary of product Characteristics (SmPC) should be consulted for further details.

**Overdose:** Excessive use may result in suppression of pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases symptomatic treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid. Accidental oral ingestion is unlikely to produce harmful effects due to the low steroid content.

**Pack size:** Diprosone Cream 30g or 100g; Diprosone Ointment 30g or 100g;  
**Legal Category:** POM. **NHS Price:** Diprosone Cream: £2.16 (30g); £6.24 (100g);  
Diprosone Ointment: £2.16 (30g); £6.12 (100g).

**Marketing Authorisation Numbers:** Diprosone Cream: 0201/0072; Diprosone Ointment: 0201/0074.

**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

*Diprosone-UK/API/11-10/4*