S-CCDS-MK1460-Dpl-MTL-082017

**Diprocel® Ointment**
Brand of betamethasone dipropionate, 0.05%
FOR DERMATOLOGIC USE ONLY

**DESCRIPTION:** Each gram of DIPROCEL Ointment contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone) in a base consisting of propylene glycol monostearate, propylene glycol, white wax and white petrolatum.

**ACTIONS:** DIPROCEL Ointment is effective because of its anti-inflammatory, antipruritic and vasoconstrictive actions. The glycol ointment vehicle increases penetration and enhances the local effectiveness of the betamethasone dipropionate.

**INDICATIONS AND USAGE:** DIPROCEL Ointment is indicated for the relief of the inflammatory manifestations of resistant or severe psoriasis and corticosteroid-responsive dermatoses.

**DOSAGE AND ADMINISTRATION:** A thin film of DIPROCEL Ointment should be applied to cover completely the affected area once daily, in the morning.

DIPROCEL Ointment may also be applied twice daily, in the morning and at night, at the physician's discretion.

As with all highly active topical corticosteroid preparations, treatment should be discontinued when the dermatologic disorder is controlled. According to clinical response, duration of therapy may vary from a few days to a longer period of time. However, treatment should not be continued for more than four weeks without patient re-evaluation.

**ADVERSE REACTIONS:** The most frequent side effect reported is mild to moderate transient folliculitis and is rare. Urticaria, increased redness of lesions, increased erythema, itching, vesiculation and pruritus have been reported.

Other local adverse reactions that have been reported with the use of topical corticosteroids include: burning, irritation, dryness, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, 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.

**CONTRAINDICATIONS:** DIPROCEL Ointment is contraindicated in those patients with a history of sensitivity reactions to betamethasone dipropionate, other corticosteroids or to any of the components of DIPROCEL Ointment.

**PRECAUTIONS:** If irritation or sensitization develops with the use of DIPROCEL Ointment, treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, an appropriate antifungal or antibacterial agent should be administered. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been controlled adequately.

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

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children. Chronic corticosteroid therapy may interfere with the growth and development of children.

DIPROCEL Ointment is not intended for used under occlusive dressings since this will also increase systemic absorption of the corticosteroid.

DIPROCEL Ointment is not for ophthalmic use.

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.

**USAGE IN PREGNANCY AND IN NURSING WOMEN:** Since safety of the use of topical corticosteroids in pregnant women has not been established, drugs of this class should not be used on pregnant patients in large amounts or for prolonged periods of time.

Caution should be exercised when DIPROCEL Ointment is administered to nursing women.

**HOW SUPPLIED:** In 5 gm, 15 gm and 100 gm tubes.
Store below 30°C.

Not all presentations may be available locally.

Further information can be obtained from the doctor or pharmacist.

**Product Registrant:**
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