BRAND OF BETAMETHASONE DIPROPIONATE, 0.05%
FOR DERMATOLOGIC USE ONLY

DESCRIPTION
Each gram of DIPROLENE Cream contains 0.64 mg betamethasone dipropionate equivalent to 0.5 mg betamethasone, in an optimized cream base containing propylene glycol. Inactive ingredients: Titanium dioxide, carboxypolymethylene, sodium hydroxide, propylene glycol, and purified water.

ACTIONS
DIPROLENE Cream provides potent anti-inflammatory, antipruritic and vasoconstrictive effects. The optimized base with the propylene glycol component increases penetration and enhances the local effectiveness of the betamethasone dipropionate.

INDICATIONS AND USAGE
DIPROLENE Cream is indicated for the relief of the inflammatory and pruritic manifestations of resistant or severe psoriasis and corticosteroidresponsive dermatoses.

DOSAGE AND ADMINISTRATION
A thin film of DIPROLENE Cream should be applied to cover completely the affected area once or twice daily (in the morning and at night). As with all highly active topical corticosteroid preparations, treatment with DIPROLENE Cream 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 effects reported are mild to moderate transient burning/stinging, dry skin, pruritus and irritation. Rarely reported adverse effects include tingling, prickly skin, tightening or cracking of skin, warm feeling, laminar scaling and perilesional scaling, follicular rash, skin atrophy, erythema and telangiectasia. Other local adverse reactions that have been reported with the use of topical corticosteroids include: itching, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

CONTRAINDICATIONS
DIPROLENE Cream is contraindicated in those patients with a history of sensitivity reactions to betamethasone dipropionate, other corticosteroids or to any of the components of DIPROLENE Cream.

PRECAUTIONS
If irritation or sensitization develops with the use of DIPROLENE Cream, 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.

DIPROLENE Cream has been shown to suppress the hypothalamic-pituitary adrenal (HPA) axis with repeated applications of 7 g/day. 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 with the use of more potent corticosteroid formulations, with prolonged usage or if extensive body surface areas are treated. Therefore, patients receiving large doses of potent topical corticosteroids applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression occurs, an attempt should be made to withdraw the drug, to reduce the frequency of
Corticosteroids can suppress pituitary-adrenal function, 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 cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

**HOW SUPPLIED**
DIPROLENE Cream, 15 and 30 grams tubes

**STORAGE**
Stored not above 25°C

**Pediatric Use:** This product is not recommended for use in children under 12 years of age. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a larger 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.

**USE DURING PREGNANCY AND IN NURSING WOMEN**
Since 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 fetus. 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.

**OVERDOSAGE**
**Symptoms:** Excessive or prolonged use of topical
should be reverted back to the conventional dosing regimen. 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
In clinical studies, DIPROLENE Ointment has been shown to be well tolerated. 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. Adverse reactions rarely reported with the use of a pulse dose regimen were mild intermittent hypertension and paresthesia. 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.

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

PRECAUTIONS
If irritation or sensitization develops with the use of DIPROLENE 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. At 14 g per day for nine days, DIPROLENE Ointment was shown to depress plasma cortisol levels following repeated applications to diseased skin in patients with psoriasis. These effects were reversible upon discontinuation of treatment. At 7 g per day (applied as 3.5 g twice daily), DIPROLENE Ointment was shown to cause minimal inhibition of the hypothalamic-pituitary-adrenal (HPA) axis when applied daily for two to three weeks in normal patients and in patients with psoriasis and eczematous disorders. With 6 to 7 g of DIPROLENE Ointment applied once daily for three weeks, no significant inhibition of the HPA axis was observed in patients with psoriasis and atopic dermatitis, as measured by plasma cortisol and 24-hour urinary 17-hydroxy corticosteroid levels.

Systemic absorption of topical corticosteroids generally will be increased with the use of more potent corticosteroid preparations, with prolonged usage or if extensive body surface areas are treated. Therefore, patients receiving large doses of potent topical corticosteroids, applied to extensive body surface areas should be evaluated periodically for evidence of HPA axis suppression. If suppression occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute with a less potent corticosteroid agent. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of corticosteroid withdrawal may occur, requiring supplemental systemic corticosteroid therapy.

Patients who are to use the pulse dose regimen to maintain remission in chronic psoriasis should be instructed specifically as to where the medication should be applied. DIPROLENE Ointment is not intended for use under occlusive dressings since this will also increase systemic absorption of the corticosteroid. DIPROLENE Ointment is not for ophthalmic use.

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OVERDOSAGE

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, 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.

HOW SUPPLIED
DIPROLENE Ointment, 15 and 30 gram tubes

STORAGE
Store between 2° and 30°C.