Diprosone* Cream/Ointment

061023742INR

Brand of betamethasone dipropionate

023742

FOR DERMATOLOGIC USE ONLY

Schering-Plough

DESCRIPTION: DIPROSONE Cream/Ointment contain in each gram betamethasone dipropionate, a synthetic corticosteroid, equivalent to 0.5 mg (0.05%) of betamethasone, in a lipid-free, paraben-free vehicle.

Inactive ingredients: Cream: Chlorocresol, sodium biphosphate, phosphoric acid, white petrolatum, mineral oil, monocetyl ether of polyethylene glycol, cetostearyl alcohol, and purified water.
Ointment: Mineral oil and white petrolatum.

ACTIONS: DIPROSONE Cream/Ointment are effective because of its anti-inflammatory, antipruritic and vasoconstrictive actions. DIPROSONE Cream/Ointment demonstrate these activities in a sustained manner thereby permitting twice-a-day or, in some cases, once-a-day application.

INDICATIONS AND USAGE: DIPROSONE Cream/Ointment are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

DOSAGE AND ADMINISTRATION: Apply a thin film of DIPROSONE Cream/Ointment to cover completely the affected area once or twice daily morning and night.

ADVERSE REACTIONS: The following local adverse reactions have been reported infrequently with the use of topical corticosteroids especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

CONTRAINDICATIONS: DIPROSONE Cream/Ointment are contraindicated in those patients with a history of sensitivity reactions to any of its components.

PRECAUTIONS: If irritation or sensitization develops with the use of DIPROSONE Cream/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 or if occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

DIPROSONE Cream/Ointment are not for ophthalmic use.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility than mature patients to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects 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 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: DIPROSONE Cream: Tubes of 10 and 30 grams
DIPROSONE Ointment: Tubes of 10 and 30 grams

STORAGE: Store between 2° and 30°C.

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