DIPROSONE® Cream and Ointment

Brand of betamethasone dipropionate

Description: Betamethasone dipropionate, a synthetic fluorinated corticosteroid, has the chemical name 9α-fluoro-16β-methylprednisolone-17, 21-dipropionate. **DIPROSONE** Cream provides in each gram 0.64 mg of betamethasone dipropionate, equivalent to 0.5 mg (0.05%) of betamethasone in a soft, white, hydrating, hypo-allergenic paraben free cream base containing white petrolatum, mineral oil, cetomacrogol 1000, cetostearyl alcohol, sodium biphosphate and phosphoric acid with chlorocresol as a preservative.

DIPROSONE Ointment provides in each gram 0.64 mg of betamethasone dipropionate, equivalent to 0.5 mg (0.05%) of betamethasone in a paraben free ointment base containing white petrolatum and mineral oil.

Actions: DIPROSONE Cream/Ointment is effective because of its anti-inflammatory, antipruritic and vasoconstrictive actions. **DIPROSONE** Cream/Ointment demonstrates these activities in a sustained manner, thereby permitting twice a day or, in some case, once-a-day application.

Indications and usage: DIPROSONE Cream/Ointment is indicated for the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses such as: psoriasis, contact dermatitis (dermatitis venenata), atopic dermatitis (infantile eczema, allergic dermatitis), neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), intertrigo, dyshidrosis (pompholyx), seborrheic dermatitis, exfoliative dermatitis, solar dermatitis, stasis dermatitis and anogenital and senile pruritus.

Dosage and administration: A thin film of **DIPROSONE** Cream/Ointment should be applied to cover completely the affected area twice daily, in the morning and at night. For some patients adequate maintenance therapy may be achieved with less frequent application. In some cases of moderate to severe psoriasis or atopic dermatitis, once-a-day application may suffice.

Adverse reactions: The following local adverse reactions have been reported with the use of **DIPROSONE** include: 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.

Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

Contraindications: DIPROSONE Cream/Ointment is contraindicated in those patients with a history of sensitivity to betamethasone dipropionate, other corticosteroids or to any of the components in these preparations.

Warnings/Precautions:

General:

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (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 potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute with 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.

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.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation or sensitization develops, treatment should be discontinued and appropriate therapy instituted.

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

DIPROSONE Cream/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.

Pediatric Use:

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroids 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 intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric 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.

Incompatibilities: No known data.

Drug Interactions: No known data.

Usage in pregnancy and nursing mothers:

Pregnancy: 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 fetus.

Nursing Mothers: It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when this product is administered to nursing mothers.

Overdosage: Excessive prolonged use of topical steroids can suppress hypothalamic-pituitary-adrenal function resulting in adrenal insufficiency. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute with a less potent steroid.

How supplied:
DIPROSONE Cream: 5 gm, 15 gm tube and 450 gm jar.
DIPROSONE Ointment: 15 gm tube.
Not all presentations may be available locally.

Store below 30°C.
Further information can be obtained from the doctor or pharmacist.

Product Registrant:
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