DIPROSALIC* Lotion

EMFA-30-in-04B

Brand of betamethasone dipropionate and salicylic acid
FOR DERMATOLOGIC USE ONLY

DESCRIPTION: DIPROSALIC Lotion contains in each gram 0.64 mg of betamethasone dipropionate, equivalent to 0.5 mg (0.05%) of betamethasone, and 20 mg (2%) of salicylic acid in a paraben-free vehicle containing isopropanol. Inactive ingredients: disodium edetate, sodium hydroxide, hydroxypropylmethylcellulose, isopropyl alcohol, and purified water. The pH is adjusted to approximately 5.0.
Salicylic acid is keratolytic and antiseptic agent.

ACTIONS: Betamethasone dipropionate, a synthetic fluorinated corticosteroid, has anti-inflammatory, antipruritic and vasoconstrictive actions.
Topical salicylic acid has keratolytic properties as well as bacteriostatic and fungicidal actions. DIPROSALIC Lotion demonstrates these actions in a sustained manner, thereby permitting twice a day application.

INDICATIONS AND USAGE: DIPROSALIC Lotion is indicated for the relief of the inflammatory manifestations of psoriasis and seborrhea of the scalp. DIPROSALIC Lotion is also indicated for the relief of inflammatory manifestations of non-scalp lesions of psoriasis and other corticosteroid-responsive dermatoses.

DOSAGE AND ADMINISTRATION: Apply a few drops of DIPROSALIC Lotion to the affected areas and massage gently and thoroughly into the sclap or the skin. The usual frequency of application is twice daily, in the morning and at night. For some patients adequate maintenance therapy may be achieved with less frequent application.

ADVERSE REACTIONS: Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infections, skin atrophy, striae, miliaria, sensation of pain, rhagades. Salicylic acid preparations may cause dermatitis.

CONTRA-INDICATIONS: DIPROSALIC Lotion is contra-indicated in those patients with a history of sensitivity reactions to any of its components.

PRECAUTIONS: If irritation or sensitization develops with the use of DIPROSALIC Lotion, treatment should be discontinued. In the presence of an infection, appropriate therapy is indicated.
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 chiidren. Systemic absorption of topical corticosteroids or salicylic acid will be increased if extensive body surface areas are treated. Application of salicylic acid to open wounds or damaged skin should be avoided.
Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children. Occlusive dressing should not be used with DIPROSALIC Lotion.
If excessive dryness or increased skin irritation develops, discontinue use of this preparation.
DIPROSALIC Lotion is not for ophthalmic use; avoid contact with eyes and mucous membranes.
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large 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.
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: 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.
Excessive or prolonged use of topical preparations containing salicylic acid may cause symptoms of salicylism.
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.
Treatment of salicylism is symptomatic. Measures should be taken to rid the body rapidly of salicylate. Administer oral sodium bicarbonate to alkalinize the urine and force diuresis.

HOW SUPPLIED: Bottles 30 ml.
Store below 30°C. Protect from light.

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Manufactured by: Memphis Co. For Pharm. & Chem. Ind. Cairo - A.R.E.
Under authority of Schering - Plough Corporation/U.S.A.