DIPROSALIC* Ointment
Schering-Plough

DESCRIPTION
DIPROSALIC Ointment provides in each gram 0.64 mg of betamethasone dipropionate, equivalent to 0.5 mg (0.05%) of betamethasone, and 30 mg (3%) of salicylic acid in a paraben free ointment base of white petrolatum and mineral oil. Salicylic acid is a keratolytic and antiseptic agent.

ACTIONS
Betamethasone dipropionate, a synthetic fluorinated corticosteroid, has anti-inflammatory, antipruritic and vasoconstrictive actions. DIPROSALIC Ointment demonstrates these actions in a sustained manner thereby permitting twice a day application.

INDICATIONS AND USAGE
DIPROSALIC Ointment is indicated for the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses such as: psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

DOSAGE AND ADMINISTRATION
A thin film of DIPROSALIC 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.

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. The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Salicylic acid preparations may cause dermatitis.

CONTRAINDICATIONS
DIPROSALIC Ointment is 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 DIPROSALIC Ointment, 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 children.

Systemic absorption of topical corticosteroids or salicylic acid will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

If excessive dryness or increased skin irritation develops, discontinue use of this preparation. DIPROSALIC Ointment is not for opthalmic use. Avoid contact with eyes and mucous membranes.

Pediatric Use: 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 hyperten-
sion 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.

Excessive or prolonged use of topical preparations containing salicylic acid may cause symptoms of salicylism.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticotoid 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 alkalinate the urine and force diuresis.

HOW SUPPLIED
Tubes of 30 grams

STORAGE
Stored not above 30°C. Protect from light.

*Trademark
DIPROSALIC* LOTION
Schering-Plough

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. The pH is adjusted to approximately 5.0.

Inactive ingredients: disodium edetate, sodium hydroxide, hydroxypropylmethylcellulose, isopropyl alcohol, and purified water. The pH is adjusted to approximately 5.0.

Salicylic acid is a keratolytic and antiseptic agent.

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

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 scalp or 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 infection, skin atrophy, striae, miliaria, sensation of pain, rhagades. Salicylic acid preparations may cause dermatitis.

CONTRAINDICATIONS
DIPROSALIC Lotion is 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 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 children.

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 Use: 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.

**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.

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**OVERDOSAGE**

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**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 of 30 ml.

**STORAGE**

Store between 2° and 25°C. Protect from light.