81–421741

Diprogenta* Cream/Ointment

Brand of betamethasone dipropionate and gentamicin sulfate.

FOR DERMATOLOGIC USE ONLY

Schering-Plough

DESCRIPTION: DIPROGENTA Cream or Ointment provide in each gram 0.64 mg of betamethasone dipropionate equivalent to 0.5 mg (0.05%) of betamethasone and gentamicin sulfate, equivalent to 1 mg (0.1%) of gentamicin base. Inactive ingredients: Cream: chlorocresol, monobasic sodium phosphate, phosphoric acid, white petrolatum, mineral oil, monocetyl ether of propylene glycol, cetostearyl alcohol, and purified water. Ointment: white petrolatum

ACTIONS: DIPROGENTA is effective because of its anti-inflammatory, antipruritic and vasoconstrictive actions. DIPROGENTA demonstrates these actions in a sustained manner, thereby permitting twice a day application.
Gentamicin, a wide spectrum bactericidal antibiotic, is effective against a broad spectrum of common skin pathogens.
Susceptible bacteria include sensitive strains of Streptococci (group A beta hemolytic, alpha hemolytic), Staphylococcus aureus (coagulase positive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria Pseudomonas aeruginosa, Aerobacter aerogenes, Escherichia coli, Proteus vulgaris, and Klebsiella pneumoniae.

INDICATIONS AND USAGE: DIPROGENTA is indicated for the relief of the inflammatory manifestations of corticosteroid responsive dermatoses when complicated by secondary infection, caused by organisms susceptible to gentamicin or when the possibility of such infections is suspected. Such disorders include: 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 DIPROGENTA 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: Reported adverse reactions with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.
Side effects occurring more frequently with occlusive dressings include: maceration of the skin, secondary infection, skin atrophy, striae and miliaria.
Treatment with gentamicin has produced transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment.

FBO

CONTRAINDICATIONS: DIPROGENTA 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 DIPROGENTA, treatment should be discontinued.
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 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.
Systemic absorption of topically applied gentamicin may be increased if extensive body surface areas are treated, especially over prolonged time periods or in the presence of dermal disruption. In these cases, the undesirable effects which occur following systemic use of gentamicin may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children.
Use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi. If this occurs or if irritation, sensitization or superinfection develops, treatment with gentamicin should be discontinued and appropriate therapy instituted.
DIPROGENTA is not for ophthalmic use.

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.
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.
A single overdose of gentamicin would not be expected to produce symptoms.
Excessive prolonged use of topical gentamicin may lead to overgrowth of lesions by fungi or nonsusceptible bacteria.

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.
Appropriate antifungal or antibacterial therapy is indicated if overgrowth occurs.

HOW SUPPLIED: Diprogenta Cream: Tube of 15 grams
Diprogenta Ointment: Tube of 15 grams

STORAGE: Store between 2° and 30°C.

Manufactured by S-P Canada Inc., Pointe-Claire, Quebec, Canada
wholly owned subsidiary of Schering-Plough Corporation/U.S.A.

*Trademark

© 11/04 Schering-Plough Corporation/U.S.A.

THIS IS A MEDICAMENT
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists