DIPROGENTA Cream/Ointment
Schering-Plough

Composition
Diprogenta Cream and Ointment provide in each gram betamethasone dipropionate equivalent to 0.5 mg (0.05%) of betamethasone and gentamicin sulfate, equivalent to 1 mg (0.1%) of gentamicin base. The cream base is composed of chlorocresol, monobasic sodium phosphate, phosphoric acid, white petrolatum, mineral oil, monocetyl ether of polyethylene glycol, cetostearyl alcohol, and purified water. The ointment base is composed of white petrolatum.

Properties
Actions
Diprogenta Cream and Ointment are effective because of their 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 Gramnegative bacteria Pseudomonas aeruginosa, Aerobacter aerogenes, Escherichia coli, Proteus vulgaris, and Klebsiella pneumoniae.

Indications
Diprogenta Cream and Ointment are indicated for the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses when complicated by secondary infections caused by organisms susceptible to gentamicin or when the possibility of such infections is suspected. Such disorders include: contact dermatitis (dermatitis venenata), atopic dermatitis (infantile eczema, allergic dermatitis), neuro-dermatitis (lichen simplex chronicus), eczema (including nummular eczema, hand eczema, eczematous dermatitis), intertrigo, dyshidrosis (pompholyx), psoriasis, lichen planus, seborrheic dermatitis, exfoliative dermatitis, solar dermatitis, stasis dermatitis, and anogenital and senile pruritus.

Contraindications
Diprogenta Cream and Ointment are contraindicated in those patients with a history of sensitivity reactions to any of their components.

Side Effects
Reported side effects 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 rarely produces transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment.

Precautions
If irritation or sensitization develops with the use of Diprogenta Cream or Ointment, 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 areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when longterm use is anticipated, 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 Cream and Ointment are not for ophthalmic 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. 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.

**Storage**

Store between 2º and 30ºC.

**Dosage and Administration**

A thin film of Diprogenta Cream or 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.