DIPROGENTA® Cream and Ointment

COMPOSITION

Each gram contains 0,64 mg betamethasone dipropionate equivalent to 0,5 mg betamethasone and 1,7 mg gentamicin sulfate equivalent to 1 mg gentamicin base.

DESCRIPTION

A combination of the corticosteroid betamethasone dipropionate and the antibiotic gentamicin sulfate with anti-inflammatory, antipruritic, vasoconstrictive and bactericidal properties, particularly against staphylococcal species.

INDICATIONS

For the reduce of inflammatory manifestations of corticosteroid-responsive dermatoses when complicated by secondary infection, caused by organisms susceptible to gentamicin, or when such infection is suspected.

DOSAGE AND ADMINISTRATION

A thin film should be applied to cover completely the affected area twice daily, in the morning and evening. Some patients may be maintained with less frequent application.

PRECAUTIONS

Discontinue treatment if irritation or sensitization develops.

Any side effect reported following use of systemic corticosteroids may occur, especially in infants and children.

Cross-allergenicity among aminoglycosides has been demonstrated.

Systemic absorption of corticosteroids will increase if occlusive dressing is used or extensive areas are treated.

Overgrowth of nonsusceptible organisms may occur; should superinfection develop, discontinue treatment and initiate appropriate therapy.

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 systemicuse of gentamicin may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children.

Not for ophthalmic use.

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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.

Not to be used for extensive body surface areas or for long-term use, because of the nephrotoxicity and ototoxicity effect.

The used of this combination more than seven days have no greater benefit than using steroid alone.

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 cortisal levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

Not to be used for children under 2 years of age.

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 inlarge 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 ofthe 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 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.

ADVERSE REACTIONS

Adverse reactions to Diprogenta Cream or Ointment therapy have been reported very rarely and include hypersensitivity and skin discoloration.

Use of topical corticosteroids have resulted in local adverse reactions, especially under occlusive dressings, include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of skin, secondary infection, skin atrophy, striae and miliaria.
Topical use of gentamicin has produced transient irritation (erythema and pruritus).

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

CONTRAINDICATIONS

Sensitivity to any ingredient.
Vaccinia, varicella, skin tuberculosis.
Not to be used for infections caused by fungi and virus.

PRESENTATIONS

DIPROGENTA Cream, tube of 5 gram; Reg. No.: DKL7606605429A1
DIPROGENTA Cream, tube of 10 gram; Reg. No.: DKL7606605429A1
DIPROGENTA Ointment, tube of 5 gram; Reg. No.: DKL7606605530A1
DIPROGENTA Ointment, tube of 10 gram; Reg. No.: DKL7606605530A1

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

Store below 30°C.

Registered and manufactured by:
PT Organon Pharma Indonesia Tbk
Pasuruan, Jawa Timur

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ORGANON

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