LPC-OG1460C-082017

DIPROGENTA® Cream

Brand of betamethasone dipropionate and gentamicin sulfate

FOR DERMATOLOGICAL USE ONLY

DESCRIPTION

DIPROGENTA Cream 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, Sodium Phosphate Monobasic Monohydrate, Phosphoric Acid, White Petrolatum, Mineral Oil, Cetostearyl Alcohol, Ceteth 20, Purified Water.

Appearance:

Cream: A smooth, white, uniform cream, free from foreign matter.

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group:

Topical corticosteroid and anti-infective in combination.

Mechanism of Action:

DIPROGENTA CREAM combines the sustained anti-inflammatory, antipruritic and vasoconstrictive actions of betamethasone dipropionate with the wide- spectrum bactericidal antibiotic activity of gentamicin sulfate.

Pharmacodynamic properties

Gentamicin, a wide spectrum bactericidal antibiotic, is effective against a broad spectrum of common skin pathogens.

Bacteria susceptible to gentamicin include sensitive strains of *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*.

Pharmacokinetic properties:

The pharmacokinetic profile of topical glucocorticoids after penetration through the skin is similar to that of systemic glucocorticoids.

Glucocorticoids bind to plasma proteins to varying degrees, are mainly metabolized in the liver and usually excreted via the kidneys.

When betamethasone dipropionate is administered intravenously to rodents, the substance and its metabolites are excreted with the feces. The substance is hence metabolized in the liver and eliminated with the bile.

Betamethasone-17-propionate and 6β-hydroxybetamethasone-17-propionate have been identified as lead metabolites.

Studies in human subjects showed that temporary lowering of plasma cortisol levels occurred only after use of more than 60 g DIPROGENTA Cream/Ointment per day on extensive body surface areas for a period of 4 weeks in subjects with psoriasis or atopic eczema.

The active drug substance gentamicin may be administered parenterally or locally. It is unsuitable for oral use because enteral absorption of the drug is minimal. Topical antibiotics are metabolized after penetration through the skin according to the same basic pattern as seen with parenteral use.

Mean peak gentamicin concentrations of 3.5-6.4 mg/L are measured 30-60 minutes after intramuscular administration of 1 mg gentamicin/kg body weight. The half-life is approx. 2 hours during the first 8-12 hours, after which gentamicin is gradually released from deep compartments at a half-life of 100-150 hours. Excretion is solely renal. The substance is excreted by glomerular filtration in an unchanged and biologically active form.

The dermal absorption rate of gentamicin after topical application of an 0.1% cream formulation to intact skin amounts to approximately 2% of the volume administered. The corresponding figure for an 0.1% ointment formulation is approximately 0.5%.

An average of 6.9 µg of gentamicin per cm2 wound surface area is absorbed from a cream formulation and approximately 1.5 µg of gentamicin from an ointment formulation. These active substance doses may result in serum concentrations of up to 1 µg/mL, corresponding to approximately 10% of the minimum toxic effect level. Serum levels of 3-4.3 µg/mL were measured after topical administration of gentamicin to burn injuries.

Because of the significant enzymatic resistance mechanism for aminoglycosides, there are numerous instances of incomplete, one-sided, and complete parallel resistances between the organisms and the various aminoglycoside antibiotics.

INDICATIONS AND USAGE

DIPROGENTA CREAM 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

Dose:

A thin film of DIPROGENTA CREAM should be applied to cover completely the affected area twice daily, in the morning and at night.

Frequency of application should be determined by the physician according to the severity of the condition. For some patients, adequate maintenance therapy may be achieved with less frequent application

Duration of Treatment:

Duration of therapy varies depending upon the extent and location of disease and patient response. However, if clinical improvement is not achieved by three to four weeks, diagnosis should be reviewed.

ADVERSE REACTIONS

Adverse reactions to DIPROGENTA CREAM have been reported very rarely and include hypersensitivity and skin discoloration.

Treatment with gentamicin has produced transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment.

Reported adverse reactions with the use of topical corticosteroids, especially under occlusive dressings, include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

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

CONTRAINDICATIONS

DIPROGENTA CREAM is contraindicated in those patients with a history of sensitivity

reactions to any of its components. Topical corticosteroids are contraindicated in vaccinia, varicella, and tuberculosis of the skin.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

If irritation or sensitization develops with the use of DIPROGENTA CREAM, treatment should be discontinued and appropriate therapy instituted.

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 occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Cross-allergenicity among aminoglycosides has been demonstrated.

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.

Prolonged 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 is not for ophthalmic use.

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.

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.

DRUG INTERACTION

No known data

PREGNANCY AND LACTATION

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 or prolonged used 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 cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

If overgrowth by non-susceptible organisms occurs, stop treatment with DIPROGENTA CREAM and institute appropriate therapy.

HOW SUPPLIED: In 5g and 15g tubes.

Not all presentations may be available locally.

STORAGE: Store below 30°C.

MANUFACTURER:

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