

QUADRIDERM* CREAM

Brand of betamethasone valerate, gentamicin sulfate, tolnaftate and clioquinol

FOR DERMATOLOGIC USE ONLY

DESCRIPTION: Each gram of QUADRIDERM Cream contains betamethasone valerate equivalent to 0.5 mg betamethasone, gentamicin sulfate equivalent to 1.0 mg gentamicin, 10 mg tolnaftate and 10 mg clioquinol (iodochlorhydroxyquin) in a paraben- and lanolin-free water washable cream base containing 0.1% chlorocresol as a preservative.

Inactive ingredients: chlorocresol, monocetyl ether of polyethylene glycol, white petrolatum, sodium phosphate, and purified water.

ACTIONS: QUADRIDERM Cream combines the anti-inflammatory, antipruritic and vasoconstrictive agent betamethasone valerate, the wide-spectrum antibiotic gentamicin sulfate, the fungicidal agent tolnaftate and clioquinol, an antibacterial and antifungal agent.

INDICATIONS AND USAGE: QUADRIDERM Cream is indicated for the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses when complicated by secondary infection caused by organisms sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected.

Such disorders include: inguinal dermatosis, chronic dermatitis of the extremities, erythrasma, balanoposthitis, herpes zoster, eczematoid dermatitis, contact dermatitis, follicular dermatitis, dyshidrosis, paronychia, anal pruritus, seborrheic eczema, intertrigo, seborrheic dermatitis, pustular acne, impetigo, neurodermatitis, angular stomatitis, photosensitivity dermatitis, lichenified inguinal dermatophytosis and tinea infections such as tinea pedis, tinea cruris and tinea corporis.

DOSAGE AND ADMINISTRATION: A thin film of QUADRIDERM Cream should be applied to cover completely the affected area two or three times daily, or as prescribed by the physician. Frequency of application should be determined according to severity of the condition.

Duration of therapy should be determined by patient response. In cases of tinea pedis, longer therapy (2-4 weeks) may be necessary.

ADVERSE REACTIONS: Local adverse reactions reported 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.

Rash, irritation and hypersensitivity have been reported with the topical usage of gentamicin sulfate, clioquinol and rarely with tolnaftate.

CONTRAINDICATIONS: QUADRIDERM Cream is contraindicated in those patients with a history of sensitivity reactions to any of its components.

PRECAUTIONS: 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 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.

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.

Prolonged use of topical antibiotics occasionally may result in overgrowth of non-susceptible organisms. If this occurs or if irritation, sensitization or superinfection develops, treatment with QUADRIDERM Cream should be discontinued and appropriate therapy instituted.





Systemic absorption of clioquinol may interfere with thyroid function tests.

The ferric chloride test for phenylketonuria can yield a false-positive result if clioquinol is present in the urine.

Slight staining of linens or clothing due to clioquinol may occur.

QUADRIDERM Cream is 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 or prolonged use of topical antibiotics may lead to overgrowth of lesions of nonsusceptible organisms.

Systemically, tolnaftate is pharmacologically inactive.

Clioquinol rarely produces iodism.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticotid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

If overgrowth by nonsusceptible organisms occurs, stop treatment with QUADRIDERM Cream and institute appropriate therapy.

HOW SUPPLIED: QUADRIDERM Cream, tube of 15 gm.

Store between 2° and 30° C.

إن هذا دواء

- الدواء مستحضر يؤخذ على صحتك واستهلاكه خلافاً للتعليمات يعرضك للخطر
 - إتبع بدقة وصفة الطبيب وطريقة الاستعمال المخصوص عليها وتعليمات الصيدلاني الذي صرفها لك فالطبيب والصيدلاني هما الخبيران بالدواء وبنفعه وضرره
 - لا تقطع مدة العلاج المحددة لك من تلقاء نفسك
 - لا تكرر صرف الدواء بدون وصفة طبية
 - لا تترك الادوية في متناول ايدي الأطفال
- مجلس وزراء الصحة العرب واتحاد الصيادلة العرب

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