LOTRIDERM* Cream

061099642INR

Brand of clotrimazole and betamethasone dipropionate

FOR DERMATOLOGIC USE ONLY

Schering-Plough

DESCRIPTION: Each gram of LOTRIDERM Cream contains 10 mg (1%) clotrimazole and 0.64 mg betamethasone dipropionate, equivalent to 0.5 mg (0.05%) betamethasone, in a cream base containing mineral oil, white petrolatum, cetostearyl alcohol, polyethylene glycol, benzyl alcohol, sodium phosphate, phosphoric acid, propylene glycol, and purified water.

ACTIONS: LOTRIDERM Cream combines the broad spectrum antifungal activity of clotrimazole with the sustained anti-inflammatory, antipruritic and vasoconstrictive actions of betamethasone dipropionate. Clotrimazole appears to act on the fungal cell membrane, causing leakage of cell contents.

INDICATIONS AND USAGE: LOTRIDERM Cream is indicated for the topical treatment of the following dermal infections: Tinea pedis, tinea cruris and tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, and Microsporum canis; candidiasis due to Candida albicans.

DOSAGE AND ADMINISTRATION: Gently massage sufficient LOTRIDERM Cream into the affected and surrounding skin areas twice a day, in the morning and evening, for two weeks in tinea cruris, tinea corporis and candidiasis, and for four weeks in tinea pedis.

DURATION OF THERAPY: Clinical improvement, with relief of erythema and pruritus, usually occurs within the first three to five days of treatment. If a patient with tinea cruris, tinea corporis, or candidiasis shows no clinical improvement after one week of treatment with LOTRIDERM Cream, the diagnosis should be reviewed. In tinea pedis, the treatment should be applied for two weeks prior to making that decision.
If the condition persists after two weeks in tinea cruris and tinea corporis, and after four weeks in tinea pedis, treatment with LOTRIDERM Cream should be discontinued. Alternate therapy may then be instituted with an appropriate antifungal agent only. The use of LOTRIDERM Cream for longer than four weeks is not recommended.

ADVERSE REACTIONS: The following adverse reactions have been reported infrequently with clotrimazole and betamethasone dipropionate when used in combination: paresthesia, maculopapular rash, edema and secondary infection.
Reported adverse reactions to clotrimazole include erythema, stinging, blistering, peeling, edema, pruritus, urticaria and general irritation of the skin.
The following local adverse reactions have been reported with the use of topical corticosteroids: 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.
Hypothalamic-pituitary adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches and bilateral papilledema.

CONTRAINDICATIONS: LOTRIDERM Cream is contraindicated in those patients with a history of sensitivity reactions to any of its components or to other corticosteroids or imidazoles.

PRECAUTIONS: LOTRIDERM Cream should not be used with occlusive dressing.
If irritation or sensitization develops with the use of LOTRIDERM Cream, treatment should be discontinued and appropriate therapy instituted.
In the presence of a bacterial infection, an appropriate antibacterial agent should be administered concomitantly. If a favorable response does not occur promptly, LOTRIDERM Cream should be discontinued until the infection has been controlled adequately.
If there is a lack of response to LOTRIDERM Cream, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy.
Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestations of Cushing's syndrome, hyperglycemia and glycosuria, may also occur with topical corticosteroids.
Systemic absorption of topical corticosteroids will be increased with the use of more potent corticosteroid agents, with prolonged usage or if extensive body surface areas are treated. Therefore, patients receiving large doses of potent topical corticosteroids, applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute with a less potent corticosteroid agent.
Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of corticosteroid withdrawal may occur, requiring supplemental systemic corticotherapy.
LOTRIDERM Cream 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.
The use of LOTRIDERM Cream in diaper dermatitis is not recommended.

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.

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.

HOW SUPPLIED: LOTRIDERM Cream tubes of 15 g. and 30 g.

STORAGE: Store between 2° and 30°C.
Manufactured by Schering-Plough Labo N.V,
Heist-op-den-Berg, Belgium,
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