Elocom* Cream, Ointment and Lotion 0.1%

Brand of mometasone furoate

FOR DERMATOLOGIC USE ONLY

DESCRIPTION: Each gram of ELOCOM Cream 0.1% contains 1 mg mometasone furoate, white petrolatum, white wax, propylene glycol stearate, stearyl alcohol and ceteareth-20, hexylene glycol, titanium dioxide, aluminum starch octenylsuccinate, purified water and phosphoric acid to adjust the pH.

Each gram of ELOCOM Ointment 0.1% contains 1 mg mometasone furoate, hexylene glycol, white wax, propylene glycol stearate, white petrolatum, purified water and phosphoric acid to adjust the pH.

Each gram of ELOCOM Lotion 0.1% contains 1 mg mometasone furoate, isopropyl alcohol, hydroxypropylcellulose, sodium phosphate monobasic, monohydrate, propylene glycol, purified water and phosphoric acid, if needed, to adjust the pH.

ACTIONS: Mometasone furoate, a synthetic corticosteroid, exhibits anti-inflammatory, antipruritic and vasoconstrictive properties.

INDICATIONS AND USAGE: ELOCOM Cream, Ointment and Lotion 0.1% are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses, such as psoriasis and atopic dermatitis. The lotion formulation may be applied to scalp lesions.

DOSAGE AND ADMINISTRATION: A thin film of ELOCOM Cream or Ointment 0.1% should be applied to the affected skin areas once daily.

Apply a few drops of ELOCOM Lotion to affected skin areas including scalp sites once daily; massage gently and thoroughly until the medication disappears.

ADVERSE REACTIONS: Local adverse reactions reported very rarely with ELOCOM Cream 0.1% include paresthesia, pruritus and signs of skin atrophy.

Local adverse reactions rarely reported with ELOCOM Ointment 0.1% include burning, pruritus, tingling/ stinging and signs of skin atrophy.

Local adverse reactions rarely reported with ELOCOM Lotion 0.l% include burning, folliculitis, acneiform reaction, pruritus and signs of skin atrophy.

The following local adverse reactions have been reported infrequently with the use of other topical corticosteroids: irritation, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

CONTRAINDICATIONS: ELOCOM Cream, Ointment and Lotion 0.1% are contraindicated in patients who are sensitive to mometasone furoate, to other corticosteroids or to any component of these preparations.

PRECAUTIONS: If irritation or sensitization develops with the use of ELOCOM products, treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection is controlled adequately.

Any of the side effects that have been 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 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. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with growth and development of children.

ELOCOM products are not for ophthalmic use.

USAGE DURING PREGNANCY AND IN NURSING WOMEN: Since safe use of ELOCOM products in pregnant women has not been established, topical corticosteroids should be used during pregnancy only if the potential benefit justifies potential risk to the fetus. Drugs of this class should not be used on pregnant patients in large amounts or for prolonged periods of time.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

OVERDOSAGE: **Symptoms:** Excessive, prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency.

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

HOW SUPPLIED: Elocom Cream, 15 and 30 gm tubes
Elocom Ointment, 15 and 30 gm tubes
Elocom Lotion: 30 ml bottles

STORAGE: Store between 2° and 30°C.

Manufactured by Schering-Plough Canada, Pointe Claire, Quebec, Canada
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