Elocon®

Mometasone Furoate

Cream, Lotion and Ointment

COMPOSITION:

Each gram of ELOCON® Cream 0.1% contains 1 mg mometasone furoate

Each gram of ELOCON® Lotion 0.1% contains 1 mg mometasone furoate

Each gram of ELOCON® Ointment 0.1% contains 1 mg mometasone furoate

ACTIONS:

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

INDICATIONS AND USAGE:

ELOCON® 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.

DOSAGE AND ADMINISTRATION:

A thin film of ELOCON® Cream or Ointment 0.1% should be applied to the affected skin areas once daily. Do not use occlusive dressing.

Apply a few drops of ELOCON® Lotion to affected skin once daily; massage gently and thoroughly until the medication disappears.

ADVERSE REACTIONS:

Local adverse reactions reported very rarely with ELOCON® Cream 0.1% include paresthesia, pruritus and signs of skin atrophy.

Local adverse reactions rarely reported with ELOCON® Lotion 0.1% include burning, folliculitis, acneiform reaction, pruritus and signs of skin atrophy.

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

The following local adverse reactions have been reported infrequently with the use of other topical corticosteroids:
Burning, pruritus, irritation, dry skin, folliculitis, hypertrichosis, acneiform eruption, 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.

PRECAUTIONS:
If irritation or sensitization develops with the use of ELOCON® 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.

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.

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.

Corticosteroid therapy can be used if therapy with less toxic drugs is not

effective. ELOCON® products are not for ophthalmic use.

USAGE DURING PREGNANCY AND IN NURSING WOMEN: Since safe use of ELOCON® 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.

CONTRAINDICATIONS:

ELOCON® 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.

PRESENTATION

ELOCON® Cream, tube of 5 g; Reg. No.: DKL9206604029A1

ELOCON® Cream, tube of 10 g; Reg. No.: DKL9206604029A1

ELOCON® Ointment, tube of 10 g; Reg. No.: DKL9406603930A1

ELOCON® Lotion, bottle of 30 ml; Reg. No.: DKL9306605041A1

HARUS DENGAN RESEP

DOKTER STORAGE

Elocon Cream & Ointment : Store below 30° C

Elocon Lotion : Store below 30° C

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

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