ELOMET® Lotion 0.1%

Brand of mometasone furoate

FOR DERMATOLOGIC USE ONLY

DESCRIPTION:

ELOMET Lotion 0.1% is a colorless to off-white lotion. Each gram of ELOMET Lotion 0.1% contains 1 mg mometasone furoate, isopropyl alcohol, hydroxypropylcellulose, sodium phosphate monobasic dihydrate, propylene glycol, purified water and phosphoric acid, if needed, to adjust the pH.

ACTION:

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

PHARMACOLOGY:

PRE-CLINICAL DATA:

Pharmacodynamics

The pharmacologic profile of mometasone furoate was determined by standard laboratory methods. Relative to betamethasone valerate, anti-inflammatory activity and anti-psoriatic activity of mometasone furoate was evaluated in mice and guinea pigs, respectively. Hypothalamic-pituitary-adrenal (HPA) axis suppression, thymolysis and skin atrophy were evaluated in mice.

In the croton oil assay in mice, mometasone furoate (ED_{50} = 0.02 µg/ear) was equipotent to betamethasone valerate after single application, and was approximately eight times as potent as betamethasone valerate after five daily applications (ED_{50} = 0.002 µg/ear/day vs 0.014 µg/ear/day). In guinea pigs, mometasone furoate was approximately twice as potent as betamethasone valerate in reducing M. Ovalis-induced epidermal acanthosis after 14 daily applications.

With respect to other pharmacologic activities commonly associated with corticosteroids, mometasone furoate (ED_{50} = 5.3 µg/ear/day) was less potent than betametasone valerate (ED_{50} = 3.1 µg/ear/day) in suppressing the HPA axis in mice after five daily application. In the thymolysis assay, mometasone furoate (ED_{50} = 26.6 µg/ear/day) was approximately two times as potent as betamethasone valerate (ED_{50} = 51.6 µg/ear/day) when applied topically, and following subcutaneous administration for five days, mometasone furoate (ED_{50} = 11.2 µg/mouse) was approximately six times as potent as betamethasone valerate (ED_{50} = 59.8 µg/mouse). At doses five to 5000 times the effective anti-inflammatory doses, mometasone furoate was three to eight times more potent than betamethasone valerate with respect to skin thinning in mice. Based on the ratio of systemic potency (HPA suppression or thymolysis) to topical anti-inflammatory potency, the therapeutic indexes for mometasone furoate were approximately three to ten times greater than those for the comparative, betamethasone valerate. Therefore, mometasone furoate would be expected to have a superior safety margin to that of betamethasone valerate.

Pharmacokinetics

The percutaneous absorption and excretion of ^{3}H-mometasone furoate cream and/or ointment was evaluated in rats, rabbits and dogs with doses ranging from 5.2 to 22 µg/cm^2. Additionally, the tissue distribution of absorbed radioactivity was determined in rabbits.

Systemic absorption of ^{3}H-mometasone furoate was minimal in all species studied, ranging from approximately 2% in dogs to 6% in rabbits over a 5 to 7-day period. The cream and ointment formulations were comparable with respect to systemic absorption. Plasma levels were low ranging from <0.1 to <1 ng/ml. Less than 1.3% of the applied dose was excreted in urine of all species and from 1.5 to 4.2% was excreted in feces. Characterization of urinary metabolites was not possible due to the low levels of drug in urine. However, it is well known that corticosteroids are metabolized to inactive water-soluble substances such as sulfate esters or glucuronides and are excreted as such. In rabbits, there was no unusual accumulation of radioactivity in any tissue.

HUMAN PHARMACOKINETICS:

Due to the occlusive nature of the ointment base, the percutaneous absorption following application of a corticosteroid ointment is greater than that of a topical corticosteroid in a cream or lotion formulation. Consequently, absorption following application of mometasone furoate lotion 0.1% is expected to be no greater than that which may occur after application of the ointment formulation.

ONSET OF ACTION:

Mometasone furoate lotion 0.1% showed rapid onset of action after one treatment week in patients with scalp psoriasis. As demonstrated by results at Day 8 in one study, improvement in total sign/symptom scores was significantly ($P<0.01$) greater in mometasone–treated patients than in those treated with betamethasone valerate 0.1%.

INDICATIONS AND USAGE:

ELOMET Lotion 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. The lotion formulation may be applied to scalp lesions.

DOSAGE AND ADMINISTRATION:

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

ADVERSE REACTIONS:

Local adverse reactions rarely reported with ELOMET Lotion 0.1% 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.

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

CONTRAINDICATIONS:

ELOMET Lotion 0.1% is 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 ELOMET Lotion, 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.

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.

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.

ELOMET Lotion is not for ophthalmic use.

USAGE DURING PREGNANCY AND IN NURSING WOMEN:

Since safe use of ELOMET Lotion 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.

DRUG INTERACTION: No known data.

INCOMPATIBILITIES: No known data.

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:

Bottles of 30 ml.

STORAGE: Store below 30°C.

Shelf-life information can be found on the outer carton of the product.
Keep medicines out of reach of children.
Jauhi ubat daripada kanak-kanak.

Further information can be obtained from the doctor or the pharmacist.

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