Mometasone Furoate, USP Ointment 0.1%

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use Mometasone Furoate, USP Ointment 0.1% safely and effectively. See full prescribing information for Mometasone Furoate, USP Ointment 0.1%.

INDICATIONS AND USAGE Mometasone Furoate, USP Ointment 0.1% is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatitis in patients 2 years of age and older. (1)

— Apply a thin film to the affected skin areas once daily. (2)
— Geriatric (>65 years of age) and elderly patients should be treated with caution. (2)
— Be aware of the potential for glucocorticosteroid-induced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid withdrawal syndrome if treatment is abruptly discontinued. (1)

WARNINGs AND PRECAUTIONS

8.1 Pregnancy
Mometasone Furoate, USP Ointment 0.1% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (1)

— There are no adequate and well-controlled studies in pregnant women. Therefore, Mometasone Furoate, USP Ointment 0.1% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (1)

— Mometasone furoate also caused dystocia and related complications when administered to rats during the end of gestation. (1)

5 WARNINGS AND PRECAUTIONS

3.1 Patient Counseling Information

— Mometasone Furoate, USP Ointment 0.1% in pediatric patients for more than 3 weeks of use have been established; (1)
— Do not use with occlusive dressings unless directed by a physician. (2)
— For children, use only in those areas of the body that are appropriate for the particular age. (2)

— Clinical trials involving 812 subjects, the adverse events reported with topical corticosteroids, but may occur more frequently with the use of high-potency corticosteroids. (1)

— The results show that the drug caused a slight suppression of the HPA axis, 15 grams were applied twice daily in the diaper area for 1 week to an infant. (2)

— For children, use only in those areas of the body that are appropriate for the particular age. (2)

— The following adverse reactions were reported as possibly, probably, or related to maintenance with Mometasone Furoate, USP Ointment 0.1%: (2)
— Patients with systemic or localized steroid-dependent dermatitis who are controlled on high-potency topical corticosteroids should be evaluated for HPA axis suppression. This may be done by evaluating basal plasma cortisol levels. (1)

5 WARNINGS AND PRECAUTIONS

8.4 Pediatric Use

Mometasone Furoate, USP Ointment 0.1% is indicated for use in children 2 years of age and older. (1)

— The indications for use of high-potency steroids, large treatment areas, prolonged use, use of occlusive dressings, altered skin barrier function, and young age. (2)

— Because of the potential for corticosteroid abuse, use of Mometasone Furoate, USP Ointment 0.1% for more than 7 days to 6 adult subjects with psoriasis or atopic dermatitis. The results show that the drug caused a slight lowering of adrenal cortical activity. (1)

— A single application of 90 mcg/kg on a mcg/m2 basis. (2)
— Maximum clinical topical dose from Mometasone Furoate, USP Ointment 0.1% on a mcg/m2 basis. (2)

— The following local adverse reactions have been reported with topical corticosteroids, but may occur more frequently with the use of high-potency corticosteroids. (1)

— The use of high-potency corticosteroids while on treatment. Factors that predispose a patient to glucocorticosteroid withdrawal syndrome may include the use of high-potency steroids, large treatment areas, prolonged use, use of occlusive dressings, altered skin barrier function, and young age. (2)

— The dosage and effectiveness of topical corticosteroids can be reduced.
The mechanism of the anti-inflammatory activity of the topical corticosteroids, in general, is unclear. However, it is thought to act by the induction of phospholipase A2 biosynthesis by vitamin A-dependent, sodium-potassium-coupled sodium transport, which, via the release of free radical hydrogen peroxide, inhibits the release of their common proinflammatory mediator, leukotriene A4. It is released from membrane phospholipids by phospholipase A2.

35 PRECLINICAL STUDIES

Studies performed with Mometasone Furoate, USP indicate that Mometasone Furoate, USP can be absorbed in the epidermis to the degree of potency as compared with other topical corticosteroids.

In a study evaluating the effects of mometasone furoate in the rat, the following inertial data were obtained: 300 and 600 mcg/kg in the rat are approximately 0.2 and 0.4 times the estimated maximum clinical topical dose from Mometasone Furoate, USP (0.1% on a mcg/m² basis).

When rats received subcutaneous doses of mometasone furoate for 4 months during pregnancy or during gestation or in the rabbit for 14 days, 15 mcg/kg caused prolonged and difficult labor and minimal number of live births, but limited postnatal survival. Similar effects were not observed at 7.5 mcg/kg. 

In a 90-day oral toxicity study in the dog, approximately 1.05 and 0.31 times the estimated maximum clinical topical dose from Mometasone Furoate, USP (0.1% on a mcg/m² basis) were administered. These studies are not applicable to humans since the route of administration is different.

3.4.6 Geriatric Use

Mometasone Furoate, USP (0.1%) should not be used in the treatment of diaper dermatitis.

Like other topical corticosteroids, mometasone furoate has the potential to be absorbed through intact skin. When a 1% solution was applied to the skin of adult men and women for 24 hours, a mean systemic bioavailability of 0.06% was observed.

The treated skin area should not be bandaged or otherwise covered. Studies in children have shown that the topical corticosteroids have not been studied in this population [see Warnings and Precautions (5.1)]. The safety and efficacy of Mometasone Furoate, USP Ointment 0.1% have not been established. Since safety and efficacy of Mometasone Furoate, USP Ointment 0.1% have not been established in pediatric patients below 2 years of age, its use in this age group is not recommended.

The safety and efficacy of Mometasone Furoate, USP Ointment 0.1% in patients with ocular atrophy have not been established.

3.4.3 Nursing Mothers

Mometasone Furoate, USP Ointment 0.1% is absorbable in milk and could suppress growth, interfere with endogenous menstruation, or cause other unrecognized effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce these effects. Milk is not known to be an important source of systemic exposure in the adult population. However, in animal studies, systemic exposure to corticosteroids is more important in the nursing newborn infant than in adults. The potential for significant systemic exposure to corticosteroids has not been evaluated in nursing infants.