Mometasone Furoate Cream 0.1% for topical use

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1. INDICATIONS AND USAGE
Mometasone Furoate Cream 0.1% is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of cortico- steroid-responsive dermatoses in patients 2 years of age or older.

2. DOSAGE AND ADMINISTRATION
Apply a thin film of Mometasone Furoate Cream 0.1% to the affected skin areas once daily. Mometasone Furoate Cream 0.1% may be used in patients younger than 2 years of age and older than 2 years of age. Results of a study in patients with acne rosacea determined that mometasone furoate cream 0.1% was effective.

3. CONTRAINDICATIONS
Mometasone Furoate Cream 0.1% is contraindicated for use on the face, groin, or axilla.

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4 CONTRAINDICATIONS

5.1 Effects on Endocrine System

5.2 Allergic Contact Dermatitis

5.3 Concomitant Skin Infections

6. ADVERSE REACTIONS

7. DRUG INTERACTIONS

8. USE IN SPECIFIC POPULATIONS

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13. PATIENT COUNSELING INFORMATION

The following adverse reactions were reported to be possibly or probably related to treatment with Mometasone Furoate Cream 0.1%.

1. The following signs of skin atrophy were also observed among 97 subjects treated with Mometasone Furoate Cream 0.1% in a clinical trial: 1). normal skin markings, 4; thinness, 1; and bruising, 1.

2. The following additional local adverse reactions have been reported with topical corticosteroids: irritation, dryness, perioral dermatitis, allergic contact dermatitis, secondary infection, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, and atrophy. The following reactions have been reported with the use of topical corticosteroids: acne vulgaris, onychomycosis and candidiasis. As with all corticosteroids, patients should be warned not to apply the medication to skin folds or other areas that may be highly sensitive to glucocorticosteroids. In a study evaluating the effects of mometasone furoate cream on the HPA axis, 13 patients were applied topical 0.1% to 2 sites to the adult subjects with psoriasis or atopic dermatitis. The results show that the drug caused a slight lowering of adrenal secretion. Systemic absorption of topical corticosteroids can produce systemic glucocorticoid insufficiency which may result in adrenocorticotropic hormone (ACTH) stimulation test.

7. DRUG INTERACTIONS

No drug-drug interaction studies have been conducted with Mometasone Furoate Cream 0.1%.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.3 Pediatric Use

8.4 Geriatric Use

8.5 Renal Impairment

8.6 hepatic Impairment

8.7 Female Reproductive Function

8.8 Effects on Growth and Development

8.9 Alterations in Laboratory Tests

9. PATIENT COUNSELING INFORMATION

10. HOW SUPPLIED/STORAGE AND HANDLING

11. CLINICAL STUDIES

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In mice, mometasone furoate caused cleft palate at subcutaneous doses of 60 mcg/kg and above. Doses of 60 mcg/kg and above produced cleft palate and/or head malformations (hydrocephaly and/or craniosynostosis) in rats. At topical doses of 140 mcg/kg, 300 mcg/kg, and 1500 mcg/kg, respectively, these effects were seen as development of hydrocephaly in the rat. The induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the release of free fatty acids from membrane phospholipids by phospholipase A2.

10terooperative Study

Studies performed with Mometasone Furoate Cream 0.1% indicate that it is in the midpoint range of potency compared to other topical corticosteroids.

In a study evaluating the effects of mometasone furoate cream on the HPA axis, 15 grams were applied daily for 4 to 7 days to 12 male and female volunteers. Corticotropin-releasing hormone (CRH) stimulation tests were performed before and after 3 days of treatment. The results showed that the drug caused a slight lowering of adrenocortical secretory response (Cortrosyn test) and suppression of ACTH was observed when treated with Mometasone Furoate Cream 0.1% at a dose of 0.003 mcg/m2/hr. A similar suppression was observed at the end of treatment with Mometasone Furoate Cream 0.1% at a dose of 0.0003 mcg/m2/hr for 2 weeks. Follow-up, taking 2 to 4 weeks after stopping treatment, available for 5 of the subjects, demonstrated only a transient effect in those subjects using these same criteria (low level of steroid suppression).

The onset of pharmacological activity of topical corticosteroids is demonstrated for many hours without reducing the surface and the intensity of the rash. The exaggerated response in the elderly is usually associated with more rapid penetration and/or higher local concentrations. Therefore, caution should be exercised when using topical preparations at higher end of the age spectrum (greater than 65 years of age). Its use in this age group is not recommended.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Like other topical corticosteroids, mometasone furoate is anti-inflammatory, antipruritic, and vasoconstrictive. These properties are attributed to the presence of the fluorine atom at C-9 of the aliphatic side-chain of the 11-deoxycortisol backbone of the molecule.

Less sensitive individuals may be at greater risk of adrenal suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are, therefore, also at greater risk of suppression of the normal adrenal function by Cortrosyn test before starting treatment, adrenal suppression was not observed at the end of treatment with Mometasone Furoate Cream 0.1% at a dose of 0.003 mcg/m2/hr during 4 weeks.

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However, greater sensitivity of some older individuals cannot be predicted on the basis of age alone, and the possibility of increased sensitivity, with the use of topical corticosteroids, must be recognized. Therefore, caution should be exercised when using topical preparations at higher end of the age spectrum (greater than 65 years of age). Its use in this age group is not recommended.

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