5.5INCH 7.5INCH

5g Cream

MOMERA

(Mometasone Furoate USP)

5g

0.1%

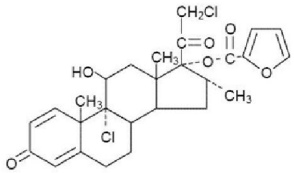
مومیرا کریم

Mometasone Furoate Cream USP 0.1%

DESCRIPTION

Mometasone furoate cream USP 0.1% contains mometasone furoate, USP for dermatologic use. Mometasone furoate is a synthetic corticosteroid with anti-inflammatory activity.

Chemically, mometasone furoate is 9α, 21-Dichloro-11β,17-dihydroxy-16α-methylpregna-1,4-diene-3,20-dione 17-(2-furoate), with the empirical formula C27H30Cl2O6, a molecular weight of 521.4 and the following structural formula:



Mometasone furoate is a white to off-white powder practically insoluble in water, slightly soluble in octanol, and moderately soluble in ethyl alcohol. Each gram of mometasone furoate cream USP 0.1% contains: 1 mg mometasone furoate USP.

CLINICAL PHARMACOLOGY

Like other topical corticosteroids, mometasone furoate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Pharmacokinetics:

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Studies in humans indicate that approximately 0.4% of the applied dose of mometasone furoate cream USP 0.1% enters the circulation after 8 hours of contact on normal skin without occlusion. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Studies performed with mometasone furoate cream USP 0.1% indicate that it is in the medium range of potency as compared with other topical corticosteroids.

INDICATIONS AND USAGE

Mometasone furoate cream USP 0.1% is a medium potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Mometasone furoate cream USP 0.1% may be used in pediatric patients 2 years of age or older, although the safety and efficacy of drug use for longer than 3 weeks have not been established. Since safety and efficacy of mometasone furoate cream USP 0.1% have not been established in pediatric patients below 2 years of age, its use in this age group is not recommended.

CONTRAINDICATIONS

Mometasone furoate cream USP 0.1% is contraindicated in those patients with a history of hypersensitivity to any of the compo¬nents in the reparation.

PRECAUTIONS

General:

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol tests. If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of mometasone furoate cream USP 0.1% should be discontinued until the infection has been adequately controlled.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Mometasone furoate also did not induce unscheduled DNA synthesis in vivo in rat hepatocytes. In reproductive studies in rats, impairment of fertility was not produced in male or female rats by subcutaneous doses up to 15 mcg/kg (approximately 0.01 times the estimated maximum clinical topical dose from mometasone furoate cream USP 0.1% on a mcg/m2 basis).

Pregnancy:

Teratogenic Effects:

There are no adequate and well-controlled studies of teratogenic effects from topically applied corticosteroids in pregnant women. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:

It is not known whether topical administration of cortico¬steroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when mometasone furoate cream USP 0.1% is administered to a nursing woman.

Pediatric Use:

Mometasone furoate cream USP 0.1% may be used with caution in pediatric patients 2 years of age or older, although the safety and efficacy of drug use for longer than 3 weeks have not been established. Use of mometasone furoate cream USP 0.1% is supported by results from adequate and well-controlled studies in pediatric patients with corticosteroid-responsive dermatoses. Since safety and efficacy of mometasone furoate cream USP 0.1% have not been established in pediatric patients below 2 years of age, its use in this age group is not recommended.

Geriatric Use:

Clinical studies of mometasone furoate cream USP 0.1% included 190 subjects who were 65 years of age and over and 39 subjects who were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

In controlled clinical studies involving 319 patients, the incidence of adverse reactions associated with the use of mometasone furoate cream USP 0.1% was 1.6%. Reported reactions included burning, pruritus, and skin atrophy. Reports of rosacea associated with the use of mometasone furoate cream USP 0.1% have also been received. In controlled clinical studies (n=74) involving pediatric patients 2 to 12 years of age, the incidence of adverse experiences associated with the use of mometasone furoate cream USP 0.1% was approximately 7%. Reported reactions included stinging, pruritus, and furunculosis.

The following adverse reactions were reported to be possibly or probably related to treatment with mometasone furoate cream USP 0.1% during clinical studies in 4% of 182 pediatric patients 6 months to 2 years of age: decreased glucocorticoid levels, 2; paresthesia, 2; folliculitis, 1; moniliasis, 1; bacterial infection, 1; skin depigmentation, 1. The following signs of skin atrophy were also observed among 97 patients treated with mometasone furoate cream USP 0.1% in a clinical study: shininess 4; telangiectasia 1, loss of elasticity 4, loss of normal skin markings 4, thinness 1, and bruising 1. Striae were not observed in this study.

The following additional local adverse reactions have been reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae, and miliaria.

OVERDOSAGE

Topically applied mometasone furoate cream USP 0.1% can be absorbed in sufficient amounts to produce systemic effects.

DOSAGE AND ADMINISTRATION

Apply a thin film of mometasone furoate cream USP 0.1% to the affected skin areas once daily. Mometasone furoate cream USP 0.1% may be used in pediatric patients 2 years of age or older. Since safety and efficacy of mometasone furoate cream USP 0.1% have not been adequately established in pediatric patients below 2 years of age, its use in this age group is not recommended.

As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. Safety and efficacy of mometasone furoate cream USP 0.1% in pediatric patients for more than 3 weeks of use have not been established.

Mometasone furoate cream USP 0.1% should not be used with occlusive dressings unless directed by a physician. Mometasone furoate cream USP 0.1 % should not be applied in the diaper area if the child still requires diapers or plastic pants as these garments may constitute occlusive dressing.

HOW SUPPLIED

Mometasone furoate cream USP 0.1 % is supplied in 5 g tubes; boxes of one.

INSTRUCTIONS:

Use as directed by the physician. Keep out of the reach of children.
Protect from light & freezing. Store at temperature between 20°C to 25°C.

ہدایات: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
بچوں کی پہنچ سے دور رکھیں۔ روشنی اور منجمد ہونے سے بچائیں۔
۲۰ سے ۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

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