Mometasone furoate ointment

Trademark Momate

Composition
Mometasone furoate 0.1% in an ointment base

Description

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

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 in a cream base of hexylene glycol, phosphoric acid, propylene glycol stearate, stearyl alcohol and ceteareth 20, titanium dioxide, aluminum starch octenylsuccinate, beeswax, white petrolatum, and purified water.

Clinical Pharmacology

Like other topical corticosteroids, mometasone furoate has anti-inflammatory, anti-pruritic, 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.

In a study evaluating the effects of mometasone furoate cream on the hypothalamic-pituitary-adrenal (HPA) axis, 15 grams were applied twice daily for 7 days to six adult patients with psoriasis or atopic dermatitis. The cream was applied without occlusion to at least 30% of the body surface. The results show that the drug caused a slight lowering of adrenal corticosteroid secretion.

In a pediatric trial, 24 atopic dermatitis patients, of whom 19 patients were age 2 to 12 years, were treated with mometasone furoate cream USP, 0.1% once daily. The majority of patients cleared within 3 weeks.

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 the drug use for longer than 3 weeks have not been established. Since safety and efficacy of mometasone furoate cream USP, 0.1% has not been established in pediatric patients below 2 years of age; its use in this age group is not recommended.
Apply a thin film of mometasone furoate cream USP, 0.1% to the affected skin areas once daily. Mometasone furoate cream USP, 0.1% should not be used with occlusive dressings. 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.

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. Manifestation 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 HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, mometasone furoate cream USP, 0.1% should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a
failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

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.

*Information for Patients:*

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped so as to be occlusive unless directed by the physician.
4. Patients should report to their physician any signs of local adverse reactions.
5. Parents of pediatric patients should be advised not to use mometasone furoate cream USP, 0.1% in the treatment of diaper dermatitis. Mometasone furoate cream USP, 0.1% should not be applied in the diaper area as diapers or plastic pants may constitute occlusive dressing.
6. This medication should not be used on the face, underarms, or groin areas unless directed by the physician.
7. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, contact the physician.
8. Other corticosteroid-containing products should not be used with mometasone furoate cream USP, 0.1% without first consulting with the physician.

_Laboratory Tests:_

The following tests may be helpful in evaluating patients for HPA-axis suppression: ACTH stimulation test, A.M. plasma cortisol test, Urinary free-cortisol test.

_Pregnancy: Teratogenic Effects: Pregnancy Category C:_

Use of mometasone furoate cream USP, 0.1% or other corticosteroids is not recommended for pregnant or nursing mothers.

_Geriatric Use:_

No overall differences in safety or effectiveness were observed between older 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.

_Presentation_

Mometasone Furoate Cream USP, 0.1% is supplied as follows:

NDC 0168-0270-15 15 gram tubes
NDC 0168-0270-46 45 gram tubes

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F)