CORTIMOM CREAM

Mometasone Furoate 0.1% Cream

COMPOSITION

Cortimom Cream contains:	
Mometasone Furoate USP	1mg
In a Translipid cream base	

DESCRIPTION

Mometasone is a medium-potency topical synthetic corticosteroid with anti-inflammatory action.

Translipid cream base is a unique combination of 70% lipids dispersed in 30% water. It spreads better, penetrates faster and stays longer; giving the power of an ointment with the comfort of a cream.

CLINICAL PHARMACOLOGY

Pharmacodynamics: Like other topical corticosteroids, Mometasone furoate has anti-inflammatory, antipruritic, and vasoconstrictive properties. Corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent inflammatory mediators such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Studies in humans indicate that approximately 0.4% of the applied dose of Mometasone Furoate Cream 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.

INDICATIONS & USAGE

Cortimom Cream 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

DOSAGE & ADMINISTRATION

Apply a thin film of **Cortimom Cream** 0.1% to the affected skin areas once daily. Therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Cortimom Cream 0.1% may be used in pediatric patients 2 years of age or older. **Cortimom Cream** 0.1% should not be used in pediatric patients below 2 years of age or for more than 3 weeks as safety and efficacy has not been adequately established.

Cortimom Cream 0.1% should not be used with occlusive dressings. **Cortimom Cream** 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.

CONTRAINDICATIONS

Cortimom Cream 0.1% is contraindicated in those patients with a history of hypersensitivity to any of the components in this preparation.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids can produce reversible 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 areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. 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. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids.

If irritation develops, Mometasone Furoate Cream 0.1% should be discontinued and appropriate therapy instituted.

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 0.1% should be discontinued until the infection has been adequately controlled.

DRUG INTERACTIONS

The combination of mometasone and anthralin topicals (used to treat psoriasis) should not be used since concomitant use may increase the symptoms of psoriasis. It is therefore advisable to discontinue topical steroids one week before starting anthralin.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of Mometasone Furoate Cream 0.1%.
Mometasone furoate was not mutagenic in the Ames test or mouse lymphoma assay, and was not clastogenic in an *in vivo* mouse micronucleus assay. 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 0.1% on a mcg/m^2 basis).

Pregnancy: Category C: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.
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: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids 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 0.1% is administered to a nursing woman.

Pediatric Use: Mometasone Furoate Cream 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 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 0.1% have not been adequately established in pediatric patients below 2 years of age, its use in this age group is not recommended.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are, therefore, also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Pediatric patients may be more susceptible than adults to skin atrophy, including striae, when they are treated with topical corticosteroids. Pediatric patients applying topical corticosteroids to greater than 20% of body surface are at higher risk of HPA axis suppression.

Geriatric Use: Clinical studies of Mometasone Furoate Cream 0.1% included subjects who were 65 years of age and over. No overall differences in safety or effectiveness were observed between these elderly subjects and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Local adverse reactions, occasionally reported with Mometasone furoate include paresthesia, folliculitis, burning, pruritus, tingling, stinging, allergic contact dermatitis, hypopigmentation, hypertrichosis, secondary infection, striae, acneiform eruptions and signs of skin atrophy.

The following additional local adverse reactions have been reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings: irritation, dryness, perioral dermatitis, maceration of the skin and miliaria.

PRESENTATION

Cortimom Cream is available in 5 g and 15 g tubes.

STORAGE

Store at a temperature not exceeding 25°C.