140 mm

210 mm

Lotion / Cream

Temoderm

(Mometasone Furoate)

0.1% w/w

طلوشن/کریم

ٹیموڈرم

(موميٹاسون فیوروایٹ)

COMPOSITION:

Temoderm Lotion 0.1% w/w

Each gram contains:

Mometasone Furoate.....1mg(0.1%)

(BP Specifications)

Temoderm Cream 0.1% w/w

Each gram contains:

Mometasone Furoate.....0.1% (1mg)

(BP Specifications)

DESCRIPTION:

Temoderm lotion 0.1% w/w and Temoderm cream 0.1% w/w contains Mometasone furoate as an active ingredient. Mometasone is a corticosteroid drug that can be used for the treatment of asthma, rhinitis, and certain skin conditions.

INDICATIONS:

Lotion:

Temoderm Lotion is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years of age or older.

Cream:

Temoderm Cream is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 2 years of age or older.

MECHANISM OF ACTION:

Like other topical corticosteroids, mometasone furoate has anti inflammatory, antipruritic, andvasoconstrictive 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 A_2 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 A_2.

DOSAGE & ADMINISTRATION:

Lotion:

Apply a few drops of mometasone furoate lotion to the affected skin areas once daily and massage lightly until it disappears.

Therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Do not use mometasone furoate lotion with occlusive dressings unless directed by a physician. Do not apply mometasone furoate lotion in the diaper area if the patient requires diapers or plastic pants, as these garments constitute occlusive dressing.

Mometasone furoate lotion is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

Avoid use on the face, groin, oaxillae. Avoid contact with eyes. Wash hands after each application.

Cream:

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

Therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Do not use mometasone furoate cream with occlusive dressings unless directed by a physician. Do not apply mometasone furoate cream in the diaper area if the patient still requires diapers or plastic pants, as these garments may constitute occlusive dressing.

Avoid contact with eyes. Wash hands after each application.

Avoid use on the face, groin, or axillae. Mometasone furoate cream is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

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 enters the circulation after 8 hours of contact on normal skin without occlusion. A similar minimal degree of absorption of the corticosteroid from the lotion formulation would be anticipated. Inflammation and / or other disease processes in the skin may increase percutaneous absorption.

WARNINGS & PRECAUTIONS:

Effects on Endocrine System

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or 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. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of high potency steroids, large treatment surface areas, prolonged use, use of occlusive dressing, altered skin barrier, liver failure and young age.

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. This may be done by using the adrenocorticotropic hormone (ACTH) stimulation test.

In a study evaluating the effects of mometasone furoate lotion on the HPA axis, 15 ml were applied without occlusion twice daily (30 mL per day) for 7 days to 4 adult subjects with scalp and body psoriasis. At the end of treatment, the plasma cortisol levels for each of the 4 subjects remained within the normal range and changed little from baseline.

In a study evaluating the effects of mometasone furoate cream on the HPA axis, 15 grams were applied twice daily for 7 days to six adult subjects with psoriasis or atopic dermatitis. The results show that the drug caused a slight lowering of adrenal corticosteroid secretion.

If HPA axis suppression is documented, an attempt should be made to gradually 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 gluco corticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

140 mm

210 mm

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

Ophthalmic Adverse Reactions

Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported in post marketing experience with the use of topical corticosteroid products, including the topical mometasone products.

Avoid contact with eyes. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

Allergic Contact Dermatitis

If irritation develops, mometasone furoate lotion and cream 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.

Concomitant Skin Infections

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 lotion and cream should be discontinued until the infection has been adequately controlled.

Pregnancy

Teratogenic Effects Pregnancy

Category C.

There are no adequate and wellcontrolled studies in pregnant women.Therefore, mometasone furoate lotion and cream 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 lotion and cream is administered to a nursing woman.

Pediatric Use

Mometasone furoate cream 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. Since safety and efficacy of mometasone furoate cream have not been established in pediatric patients below 2 years of age, its use in this age group is not recommended.

Since safety and efficacy of mometa-sone furoate lotion have not been established in pediatric patients below 12 years of age, its use in this age group is not recommended.

SIDE EFFECTS:

Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Postmarketing reports for local adverse reactions to topical corticosteroids include irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and miliaria. These adverse reactions may occur more frequently with the use of occlusive dressings.

Postmarketing reports for ophthalmic adverse reactions to topical corticosteroids include blurred vision, cataracts, glaucoma, increased intraocular pressure, and central serous chorioretinopathy.

DRUG INTERACTIONS:

No drug-drug interaction studies have been conducted with mometasone furoate lotion and cream.

CONTRAINDICATIONS:

The use of mometasone furoate lotion and cream is contraindicated in those patients with a history of hypersensitivity to any of the components in the preparation.

STORAGE & INSTRUCTIONS:

Store below 25°C. Do not freeze or refrigerate.

Protect from heat, sunlight and moisture.

Avoid contact with the eyes.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

Temoderm Lotion 0.1% w/w: 20ml

Temoderm Cream 0.1% w/w : 5g

خوراک وہدایات:

دوا کو ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ دھوپ، گرمی، نمی اور منجمد ہونے سے بچائیں۔ ریفریجریٹر میں نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549,Sundar Industrial Estate,

Lahore, Pakistan.