

# MOTESONE CREAM

## MOTESONE CREAM 0.1% w/w

### Composition:

Motesone Cream contains Mometasone furoate U.S.P. 0.1% w/w

### Pharmacological Properties:

#### Pharmacodynamics

Mometasone furoate is a potent glucocorticoid from Group III. The active substance, Mometasone furoate is a synthetic, non-fluorinated glucocorticoid which exhibits marked anti-inflammatory activity and marked anti-psoriatic activity.

#### Pharmacokinetics

Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone furoate cream 0.1% is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application.

#### Indications:

Motesone Cream is indicated for the treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis.

#### Dosage and administration:

*Adults, including elderly patients and Children:* A thin film of Motesone Cream should be applied to the affected areas of skin once daily.

*Children below 2 years of age:* Use of Motesone Cream is not recommended.

Use of topical corticosteroids in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

#### Contraindications:

Motesone cream is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyoderma), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions.

Motesone cream should not be used on wounds or on skin which is ulcerated.

Motesone cream should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids.

#### Side effects:

Local adverse reactions rarely reported with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasiae.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

#### Use in pregnancy and lactation

During pregnancy and lactation, treatment with Motesone cream should be performed only on the physician's order. Then however, the application on large body surface areas or over a prolonged period should be avoided.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. If treatment with higher doses or long term application is indicated, breast-feeding should be discontinued.

Motesone cream should be used in pregnant and lactating women only if the potential benefit justifies the potential risk to the mother or the foetus/child.

#### Precautions:

- If irritation or sensitisation develop with the use of Motesone, treatment should be withdrawn and appropriate therapy instituted.

- If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days and occlusion should

not be used. Long term continuous therapy should be avoided in all patients irrespective of age.

- As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment.

- Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

- Motesone cream is not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

#### Presentation:

Motesone Cream is available in a 15g aluminium collapsible tubes.

#### Storage:

Store below 30°C. Keep out of the reach of children. Replace the cap after use. Wash hands after use.

Manufactured by:



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