

For the use of Registered Medical Practitioner or a Hospital or a Laboratory only.

Mometasone Cream I.P. 0.1% W/W

Motimesh™
मोटिमेश
Cream

PATENTED*

In a Cream Matrix with **BIOCHITODERM™**

FOR EXTERNAL USE ONLY

COMPOSITION:

Mometasone Furoate I.P. 0.1 % w/w

in a cream base containing

Biopolymer (Poly-β-(1,4)-2-amino-2-deoxy-D-glucose) qs.

Preservatives:

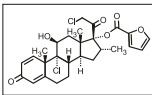
Methylparaben I.P. 0.2 % w/w

Propylparaben I.P. 0.02 % w/w

BIOCHITODERM™

PRODUCT DESCRIPTION:

Each gram of **Motimesh** cream contains Mometasone Furoate I.P. 1 mg/g (0.1 % w/w), in a cream base containing **(BIOCHITODERM™)** Biologically active Polymer, a linear polysaccharide. Mometasone Furoate is a synthetic corticosteroid with anti-inflammatory activity. Chemically it is 9α,21-Dichloro-11β-hydroxy-16α-methyl-3,20-dioxopregna-1,4-dien-17-yl furan-2-carboxylate with molecular formula $C_{32}H_{42}Cl_2O_6$, its molecular weight is 521.4. It has the following structural formula:



Mometasone Furoate is a white to off-white powder practically insoluble in water, slightly soluble in ethanol (95%) and soluble in acetone and in dichloromethane.

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION:

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 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 .

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 Mometasone Furoate 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:

Used to treat a variety of skin conditions like eczema, dermatitis, allergies, rash and inflammation of corticosteroid responsive dermatoses. Mometasone Furoate reduces the swelling, itching, and redness that can occur in these types of conditions.

DOSAGE AND ADMINISTRATION:

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

It should not be used with occlusive dressings unless directed by a Physician.

ADVERSE EFFECTS:

The following are some of the side effects that are known to be associated with

Motimesh cream:

- Thinning of the skin
- Changes in skin pigmentation
- Pins and needles (Paraesthesia)
- Acne/pimples/lumps on the skin/blisters containing pus
- Allergic inflammation of the skin (Contact Dermatitis)
- Stretch marks (Striae) or Streaks on the skin
- Excessive hair growth (Hypertrichosis)
- Inflammation of the hair follicles (Folliculitis)
- Itching/Temporary burning and stinging on application
- Redness/numbness/Dry Skin

STORAGE:

Store at temperatures below 25°C. Do not freeze. Keep out of reach of children.

SHELF LIFE:

24 Months.

PRESENTATION:

Motimesh cream is available in collapsible aluminium tube internally coated with epoxy based lacquer, with polypropylene cap of 15g & 5g in an attractive individual carton.

SALIENT FEATURES OF **Motimesh** Cream

Skin friendly Bio-Polymer **BIOCHITODERM™** in **Motimesh** cream

- Forms a Micro film at affected site and offers skin protection.
- Cationic charge immobilizes microbes at affected site.
- Proven rapid and complete re-epithelialization of skin at affected site.

IN-VIVO BIOEQUIVALENCE STUDY

Evaluation of in-vivo bioequivalence, by comparison of Vasoconstriction caused by **Motimesh** cream with marketed product. Based on the results obtained from evaluable subjects the 90 % confidence interval range of **Motimesh** cream for bioequivalence is 88.5 % -112.6 %, which is within the 90 % Confidence interval for bioequivalence as suggested by US-FDA guidelines (80 % - 125 %). Hence **Motimesh** cream is bioequivalent to marketed product.

CLINICAL STUDY

Clinical study was conducted to compare and evaluate the efficacy of **Motimesh** cream with marketed product in patients with inflammatory and Pruritic manifestations of corticosteroid-responsive dermatoses.

- Visual Analogue Scale Score data shows that **Motimesh** cream is scored 1.3 whereas marketed product is scored 2.4 at visit 3, it clearly indicates that severity of affected site is lesser in **Motimesh** cream.
- Global Score Index data confirms that **Motimesh** cream is scored 0.2 whereas marketed product is scored 1 at visit 3; it clearly indicates that the score is lesser in **Motimesh** cream.
- Physician's Global Evaluation Score shows that 60 % population achieved excellent results for **Motimesh** cream treated group. But only 20 % population achieved excellent results for marketed product treated group.
- Patient's Compliance confirmed that 40 % of the study population has achieved score zero i.e. absence of signs of itching or indication of pain and 60 % of the study population has achieved score one i.e. evidence of mild itching and irritation from the group that received **Motimesh** cream. For marketed product, 40 % of study population achieved score zero i.e. absence of signs of itching or indication of pain and 30% of the study population has achieved score one i.e. evidence of mild itching and irritation, 30 % of the study population has achieved score two i.e. evidence of moderate itching and irritation.

Based on all the above assessments and evaluations, **Motimesh** cream has scored better, adding value to the treatments given so far to the patients with Skin infections (eczema, dermatitis, allergies, rash), inflammatory and Pruritic manifestations of corticosteroid responsive dermatoses.

From the clinical study concluded that **Motimesh** cream enhances superior therapeutic activity better than marketed product.

* Patent granted in India (424443)

apex®

Manufactured in India by:

apex laboratories private limited

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