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

Sodium Fusidate & Mometasone Furoate Cream

Motimesh-SF™

मोटिमेश-एस एफ

Cream

PATENTED*

In a Cream Matrix with **BIOCHITODERM®**

FOR EXTERNAL USE ONLY

COMPOSITION:

Sodium Fusidate I.P. equivalent to Fusidic Acid 2 % w/w

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.

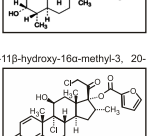
Preservative:

Benzoic Acid I.P. 0.2 % w/w

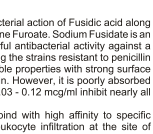
BIOCHITODERM®

PRODUCT DESCRIPTION:

Each gram of Motimesh-SF cream contains a combination of Sodium Fusidate I.P. equivalent to Fusidic Acid 20 mg/g (2 % w/w) and Mometasone Furoate 1 mg/g (0.1 % w/w) in a cream base containing (**BIOCHITODERM®** Biologically active Polymer), a linear polysaccharides. Sodium Fusidate is Sodium (17Z) β-16-acetoxy-3α, 11α-dihydroxyfusida-17(20), 24-dien-21-oate; a white or almost white crystalline powder, slightly hygroscopic and freely soluble in water and alcohol. Chemically, Sodium Fusidate is $C_{31}H_{47}NaO_6$. It has the following structural formula:



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; a white to off-white powder practically insoluble in water, slightly soluble in ethanol (95%) and soluble in acetone and in dichloromethane. Chemically, Mometasone Furoate is $C_{27}H_{30}Cl_2O_6$. It has the following structural formula:



CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION:

Motimesh-SF cream combines the potent topical anti-bacterial action of Fusidic acid along with the anti-inflammatory & anti-pruritic effects of Mometasone Furoate. Sodium Fusidate is an antibiotic derived from Fusidium coccineum, exert a powerful antibacterial activity against a number of gram-positive organisms. Staphylococci, including the strains resistant to penicillin or other antibiotics. Fusidic acid exhibits fat and water soluble properties with strong surface activity and shows unusual ability to penetrate the intact skin. However, it is poorly absorbed systemically after topical administration. Concentration of 0.03 - 0.12 mcg/ml inhibit nearly all strains of Staphylococcus aureus.

Unbound corticosteroids cross the cell membranes and bind with high affinity to specific cytoplasmic receptors. The result includes inhibition of leukocyte infiltration at the site of inflammation, interference in the function of mediators of inflammatory response, suppression of humoral immune responses and reduction in edema or scar tissue. The anti-inflammatory actions of corticosteroids are thought to involve phospholipase A2 inhibitory proteins, lipocortins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes.

Pharmacodynamics

Fusidic acid disrupts translocation of peptide subunits and elongating the peptide chain of susceptible bacteria, thus inhibiting protein synthesis. The Biopolymer demonstrates blood clotting, film forming, wound healing and skin restoration properties.

Pharmacokinetics

In-vitro studies show that Fusidic acid can penetrate intact human skin in concentration well above the MIC- values of susceptible organisms. The degree of exposure depends on factors such as the duration of exposure to Fusidic acid and the condition of the skin. The major route of elimination of Fusidic acid is through the biliary tree and faeces with less than 1 % of the administered dose excreted by urine in microbiologically active form. Approximately 2% of the administrated dose is detected as unchanged drug in the faeces. The steroid-like structure of Fusidic acid confers certain advantages, such as good skin penetration. Fusidic acid penetrates normal, damaged and avascular skin. Topical administration of Fusidic acid results in much higher local concentrations than can be achieved with systemic administration and antimicrobial concentrations of Fusidic acid can be achieved even at deeper layers of the epidermis or dermis.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and integrity of the epidermal barrier. Studies in humans indicate that Mometasone Furoate enters a 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:

Motimesh-SF cream is used to treat the eczema and dermatitis that are infected with bacteria. The Mometasone Furoate reduces the inflammation in the skin while the Fusidic Acid treats the infection.

CONTRAINDICATION:

Motimesh-SF Cream is contraindicated in those patients with a history of hypersensitivity to any of the components in the preparation. Topical steroids are contraindicated in untreated fungal, bacterial and viral (i.e. herpes simplex, chicken pox and vaccinia) infections involving the skin.

Infection caused by non-susceptible organisms, in particular, Pseudomonas aeruginosa.

ADVERSE EFFECTS:

Fusidic acid is remarkably well tolerated and there is an extremely low frequency of hypersensitivity reaction.

The following are some of the side effects that are known to be associates with Mometasone Furoate:

- 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

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.

Mometasone Furoate is known to interact with other drugs like Itraconazole, Prednisolone and Prednisone. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

DOSAGE AND ADMINISTRATION:

Apply a thin layer of **Motimesh-SF** Cream to the affected skin once or twice daily. Normally, a single treatment course should not exceed 2 weeks.

PRESENTATION:

Motimesh-SF Cream is available in collapsible aluminum tube internally coated with epoxy based lacquer, with polypropylene cap of 10 g in an attractive carton.

STORAGE:

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

SHELF LIFE:

24 Months

SALIENT FEATURES OF **Motimesh-SF** Cream

Skin friendly Bio-Polymer **BIOCHITODERM®** in **Motimesh-SF** cream

- Forms a Micro film at affected site and offers skin protection
- Facilitates rapid clotting of blood at affected site
- Cationic charge immobilizes microbes at affected site
- Ensures proven rapid and complete re-epithelialization of skin at affected site

***IN-VIVO* BIOEQUIVALANCE STUDY:**

Evaluation of *In-vivo* bioequivalence by comparison of Vasoconstriction caused by **Motimesh-SF** cream with marketed product was carried out. Based on the results obtained from the evaluated subjects the 90% confidence interval range of **Motimesh-SF** cream for bioequivalence is 89.30%-103.09%, which is within the 90% confidence interval for bioequivalence suggested by USFDA guideline (80%-125%). Hence **Motimesh-SF** Cream is bioequivalent to marketed product.

CLINICAL STUDY:

Clinical study was conducted to compare and evaluate the efficacy of the **Motimesh-SF** cream with marketed product in patients having infected eczema.

a. Visual Analogue scale score data shows that **Motimesh-SF** cream is scored 2.4 whereas marketed product is scored 3.0 at visit 3; it clearly indicates that severity of the affected site is lesser in **Motimesh-SF** cream.

b. Global Score Index data confirms that **Motimesh-SF** cream is scored 1.2 whereas marketed product is scored 2.0 at visit 3; it clearly indicates that the score is lesser in **Motimesh-SF** cream.

c. Physician's Global Evaluation Score shows that 50 % population achieved excellent results for **Motimesh-SF** cream treated group. But none of the population achieved excellent results for marketed product treated group at visit 3.

d. Patient's Compliance confirmed that 50 % of the study population has achieved score zero i.e. absences of signs of itching or indication of pain from the groups that received **Motimesh-SF** cream. For the Marketed Product, no one has achieved the excellent results at visit 3.

e. Skin Infection Rating Scale data shows that **Motimesh-SF** cream is scored 2.3 whereas marketed product is scored 7.1 at visit 3; it clearly indicates that the score is lesser in **Motimesh-SF** cream.

Based on all the above assessments and evaluations, **Motimesh-SF** cream has scored better, adding value to the treatments given so far to the patients with infected eczema.

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

apex®

*Patent granted in India (392812)

Manufactured in India by:

apex laboratories private limited

B-23, SIDCO Pharmaceutical Complex, Alathur - 603110, Tamil Nadu.

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