

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

Halobetasol Propionate Cream 0.05 % w/w

HalomeshTM हालोमेश
Cream

In a Cream Matrix with **BIOCHITODERM**[®]

PATENTED*

FOR EXTERNAL USE ONLY

COMPOSITION:

Halobetasol Propionate U.S.P. 0.05 % w/w

in a cream base containing

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

Preservatives:

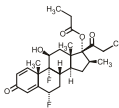
Methylparaben I.P. 0.2 % w/w

Propylparaben I.P. 0.02 % w/w

BIOCHITODERM[®]

PRODUCT DESCRIPTION:

Each gram of **Halomesh** cream contains Halobetasol Propionate U.S.P. 0.05 % w/w, in a cream base containing (**BIOCHITODERM**[®] Biologically active polymer), a linear polysaccharide. Halobetasol Propionate is 21-chloro-6α,9-difluoro-11β,17-dihydroxy-16β-methylpregna-1,4-diene-3,20-dione, 17-propionate; white to off-white powder. Freely soluble in dichloromethane and in acetone; practically insoluble in water. Chemically Halobetasol Propionate is C₂₈H₃₇ClF₂O₆. It has the structural formula.



PHARMACOLOGICAL PROPERTIES:

Halomesh cream is a very high potency topical corticoid with anti-inflammatory, antipruritic and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical corticosteroids, in general, is unclear.

However, corticosteroids are thought to act by the induction of phospholipase A₂ 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 A₂.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Studies performed with Halobetasol propionate cream indicate that it is in the super-high range of potency as compared with other topical corticosteroids.

INDICATIONS:

Halomesh cream is used to treat a variety of skin conditions like

- eczema
- dermatitis
- allergies and rash

Halomesh cream reduces the swelling, itching and redness that can occur in these types of conditions.

DOSAGE AND ADMINISTRATION:

Apply a thin layer of **Halomesh** cream to the affected skin once or twice daily, as directed by your physician, and rub in gently and completely. **Halomesh** cream is a super-high potency topical corticosteroid; therefore, treatment should be limited to two weeks, and amounts greater than 50g per week should not be used. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within two weeks, reassessment of diagnosis may be necessary. **Halomesh** cream should not be used with occlusive dressings.

DRUG INTERACTIONS

None well documented.

ADVERSE EFFECTS:

In controlled clinical trials, the most frequent adverse events reported for Halobetasol propionate cream included stinging, burning or itching in 4.4 % of the patients. Less frequently reported adverse reactions were: dry skin, erythema, skin atrophy, leukoderma, vesicles and rash. The following additional local adverse reactions are reported infrequently with topical corticosteroids, and they may occur more frequently with high potency corticosteroids, such as Halobetasol propionate cream. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

STORAGE:

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

SHELF LIFE:

24 Months.

PRESENTATION:

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

SALIENT FEATURES OF Halomesh Cream

Skin friendly Bio-Polymer **BIOCHITODERM**[®] in **Halomesh** cream

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

CLINICAL STUDY

Clinical trial was conducted comparing the efficacy of **Halomesh** cream with marketed product in patients with inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

- Visual Analogue Scale (VAS) Score for **Halomesh** cream is 1.5 whereas marketed product is 2.9 at visit 3; it clearly indicates that severity of wound is lesser in **Halomesh** cream treated group.
- Global Score Index for **Halomesh** cream is 0.9 whereas marketed product is 1.8 at visit 3; it clearly indicates that the score is lesser in **Halomesh** cream treated group.
- Physician's Global Evaluation Score (PGES) shows that 80 % of the population with **Halomesh** cream achieved excellent results but only 20 % achieved excellent results with marketed product at visit 3.
- Summary statistics of patient's compliance confirmed that 30 % of the study population has achieved score zero i.e. absence of signs of itching or indication of pain and score one i.e. evidence of mild itching and irritation from the group that received **Halomesh** cream but only 20 % of study population achieved the same with marketed product at visit 3.
- Skin Infection Rating Scale Score for **Halomesh** cream is 2 whereas marketed product is 3.3 at visit 3; it clearly indicates that the score is lesser in **Halomesh** cream treated group.

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

- PATENT Granted in India (361609)

apex[®]

Manufactured in India by:
apex laboratories private limited
B-23, SIDCO Pharmaceutical Complex, Alathur - 603 110, Tamil Nadu.

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B2PMS053/00