

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

Halobetasol Propionate & Salicylic Acid Ointment

Halomesh™ हालोमेश-एस
Ointment

In an Ointment Matrix with **BIOCHITODERM®**

FOR EXTERNAL USE ONLY

COMPOSITION:

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

Salicylic Acid I.P. 6 % w/w

in an ointment base containing Biopolymer

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

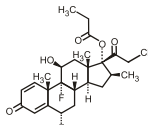
Preservative: Benzyl Alcohol I.P. 0.5 % w/w

BIOCHITODERM®

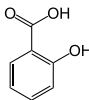
PRODUCT DESCRIPTION:

Each gram of **Halomesh-S** Ointment contains a Halobetasol Propionate U.S.P. 0.05% w/w and Salicylic Acid I.P. 6% w/w in an ointment base containing **(BIOCHITODERM®** Biologically active Polymer), a linear polysaccharides.

Halobetasol Propionate is 21-chloro-6α,9 difluoro-11β,17dihydroxy-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 C₂₈H₃₈ClF₂O₆. It has the structural formula.



Salicylic Acid is 2-hydroxy benzoic acid, white or colourless, acicular crystals or a white crystalline powder. Freely soluble in ethanol (95%) and in ether; sparingly soluble in chloroform; slightly soluble in water. Chemically salicylic acid is C₇H₆O₃.



PHARMACODYNAMICS:

Halomesh-S Ointment is combination of Salicylic Acid and Halobetasol Propionate. Salicylic Acid is a Keratolytic (peeling) agent. Salicylic Acid causes shedding of the outer layer of skin. Halobetasol Propionate is a very high potency topical corticosteroid with Anti-inflammatory, Antipruritic and Vasoconstrictive properties.

Salicylic Acid directly and irreversibly inhibits the activity of both types of Cyclooxygenases (COX-1 and COX-2) to decrease the formation of precursors of prostaglandins and Thromboxane from Arachidonic acid. Salicylate may competitively inhibit prostaglandin formation. Salicylate's Anti-rheumatic (Non-steroidal Anti-inflammatory) actions are a result of its analgesic and anti-inflammatory mechanisms. It works by causing the cells of the epidermis to slough off more readily, preventing pores from clogging up, and allowing room for new cell growth.

The mechanism of the Halobetasol Propionate is Anti-inflammatory activity of the topical Corticosteroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipids, 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:

Salicylic Acid is readily absorbed from the skin. 50 to 80% of Salicylate in the blood is bound to plasma proteins, while the rest remains in the active ionized state. The apparent volume of distribution is 0.1 to 0.2L/kg. Acidosis increases the volume of distribution because of the enhancement of tissue penetration of Salicylate. The plasma Salicylate half-life following therapeutic doses is 2 to 4.5 hours. Approximately 80% of Salicylic Acid is metabolized in the liver. Salicylates are excreted mainly by the kidney as Salicylic Acid, Salicylic Acid, Salicylic glucuronides and gentisic acid.

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 and Salicylic Acid Ointment indicates that it is in the super-high range of potency as compared with other topical corticosteroids.

INDICATIONS:

Halomesh-S Ointment is used to treat inflammation, redness and itching caused by a number of skin conditions such as eczema, allergic reactions, dermatitis, rashes and psoriasis. It is also used to treat several autoimmune diseases including lichen planus, lichen sclerosis.

CONTRAINDICATION:

Halomesh-S Ointment 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*.

Salicylic Acid is used topically. It may cause an allergic contact rash in some people. If applied to large areas of skin, it may be absorbed into the blood stream and induce toxicity (Salicylism).

DOSAGE AND ADMINISTRATION:

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

DRUG INTERACTIONS:

Salicylic Acid is highly protein-bound and may increase the unbound or free drug concentrations of other drugs such as Hypoglycemics, Anticoagulants and Methotrexate (an Antimetabolite Chemotherapeutic drug), reaching toxic levels of these agents.

ADVERSE EFFECTS:

Salicylic Acid may induce allergic contact dermatitis. Salicylic Acid may cause excessive drying and irritation in some people. Some individuals, especially Asthmatics exhibit sensitivity to Salicylates. Urticaria, Angioneurotic Oedema, Rhinitis, severe and even fatal proxyrsalm, Bronchospasm and Dyspnea may occur.

Lesser 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. 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 milaria.

STORAGE:

Store at a temperature not exceeding 30°C. Do not freeze. Keep out of reach of children.

SHELF LIFE:

24 Months

PRESENTATION:

Halomesh-S Ointment is available in collapsible aluminium tube internally coated with epoxy based lacquer, with polypropylene cap of 20 g in an attractive carton.

apex®

Manufactured in India by:

apex laboratories private limited
B-23, SIDCO Pharmaceutical Complex,
Alathur - 603 110, Tamil Nadu.

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