

EntezmaTM Ointment

Centaur

DESCRIPTION

Entezma Ointment is a combination of betamethasone dipropionate and salicylic acid. Betamethasone dipropionate is a synthetic corticosteroid that has anti-inflammatory, antipruritic and vasoconstrictive actions. Topical salicylic acid is a keratolytic agent that also has bacteriostatic and fungicidal actions. **Entezma Ointment** demonstrates these actions in a sustained manner thereby permitting twice a day application.

COMPOSITION

Each gram of **Entezma Ointment** contains:
Betamethasone (as Dipropionate) BP 0.5 mg
Salicylic Acid BP 30 mg

PHARMACOLOGY

Corticosteroids are used primarily for their anti-inflammatory and/or immunosuppressive effects. **Entezma Ointment** is effective in the treatment of corticosteroid-responsive dermatoses primarily because of its anti-inflammatory, antipruritic, and vasoconstrictive actions.

INDICATIONS

Entezma Ointment is indicated for the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses such as: psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

DOSAGE & ADMINISTRATION

A thin film of **Entezma Ointment** should be applied twice daily, in the morning and at night, to cover completely the affected area. For some patients, adequate maintenance therapy may be achieved with less frequent application.

CONTRAINDICATIONS

Entezma Ointment is contraindicated in those patients with a history of sensitivity reactions to any of its components.

PRECAUTIONS

If irritation or sensitization develops with the use of **Entezma Ointment**, treatment should be discontinued. In the presence of an infection, appropriate therapy is indicated.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Systemic absorption of topical corticosteroids or salicylic acid will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

If excessive dryness or increased skin irritation develops, discontinue use of this preparation.

Entezma Ointment is not for ophthalmic use. Avoid contact with eyes and mucous membranes.

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

PREGNANCY

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

LACTATION

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug taking into account the importance of the drug to the mother.

ADVERSE REACTIONS

Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.

The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Salicylic acid preparations may cause dermatitis.

OVERDOSAGE

Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

Excessive or prolonged use of topical preparations containing salicylic acid may cause symptoms of salicylism.

PRESENTATION

Entezma Ointment is available in a tube of 15 g and 30 g.

STORAGE

Store at temperature between 15-30°C in a dry place.

Keep medicines out of reach of children.

Puncture nozzle seal with piercing point of cap.

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Manufactured by:

CENTAUR PHARMACEUTICALS PVT. LTD.

Plant - II, Plot No.39-41, Tivim Industrial Estate,
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TM Trade Mark

Actual Size : L 106+106 x H 145 mm

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