SUMMARY OF PRODUCT CHARACTERISTICS

ENTEZMA OINTMENT

1. NAME OF THE MEDICINAL PRODUCT

ENTEZMA OINTMENT

Entezma is a combination of Betamethasone dipropionate 0.5 milligram and Salicylic acid 30 milligram in the form of a white, smooth homogenous ointment.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Betamethasone (as dipropionate) BP.....0.5 mg
Salicylic Acid BP.....30 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

White, smooth homogenous ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Posology and method of 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.

Paediatric population:

The application is same as above.

Refer section 4.4 – Special warnings and precautions for use.

4.3 Contraindications

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the Entezma presentations contraindicates their use in most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. Entezma should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

4.4 Special warnings and precautions for use

Occlusion must not be used, since under these circumstances the keratolytic action of salicylic acid may lead to enhanced absorption of the steroid.

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

It is dangerous if Entezma presentations come into contact with the eyes. Avoid contact with the eyes and mucous membranes.

The systemic absorption of betamethasone dipropionate and salicylic acid may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.

If irritation or sensitisation develops with the use of Entezma Ointment treatment should be discontinued.

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

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

Paediatric Use: Paediatric 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.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, Pregnancy and lactation

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 foetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

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.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Entezma skin preparations are generally well tolerated and side effects are rare.

Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

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.

In addition, prolonged use of salicylic acid preparations may cause dermatitis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https:// pv.pharmacyboardkenya.org.

4.9 Overdose

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

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

With topical preparations containing salicylic acid excessive prolonged use may result in symptoms of salicyclism. Treatment is symptomatic. Measures should be taken to rid the body rapidly of salicylate. Administer oral sodium bicarbonate to alkalinise the urine and force diuresis.

The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Entezma preparation contains the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids, and salicylic acid which has keratolytic properties.

Betamethasone dipropionate

Therapeutic subgroup: D07 – Dermatological corticosteroids

Pharmacological subgroup: D07A – Corticosteroids, plain

Chemical subgroup: D07AC – Corticosteroids, potent

The ATC code of Betamethasone dipropionate is D07AC01. In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

Salicylic acid:

Therapeutic subgroup: D11 – Other dermatological preparations

Pharmacological subgroup: D11A – Other dermatologicals

Chemical subgroup: D11AF - Keratolytics

The ATC code of Salicylic acid is D11AF02. Salicylic acid is applied topically in the treatment of hyperkeratotic and scaling conditions where its keratolytic action facilitates penetration of the corticosteroid.

5.2 Pharmacokinetic properties

Salicylic acid exerts only local action after topical application.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Lactate solution

Lactic Acid

Polymeg 1500 PH

Polymeg 4000

Polymeg 400.

6.2 Incompatibilities

None.

6.3 Shelf life

Three years from the date of manufacture.

6.4 Special precautions for storage

Do not store above 30°C. Protect from light and moisture.

6.5 Nature and contents of container

ENTEZMA Ointment is filled in well labelled aluminium collapsible tubes, which are packed in well labelled cartons.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorisation Holder:
M/s. Centaur Pharmaceuticals Pvt. Ltd.
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Karaswada, Mapusa, Goa- 403526,
India.

8. MARKETING AUTHORISATION NUMBER(S)

H2010/22195/791

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of First Registration: 10/10/2005

10. DATE OF REVISION OF THE TEXT

18/6/2026