1.6 Product information

1.6.1 Prescribing information (Summary of Product Characteristics)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

ENTEZMA OINTMENT.

1.1 Strength:

Composition:

Each gram contains:

Betamethasone (as dipropionate) BP……0.5 mg

Salicylic Acid BP……...30 mg

1.2 Pharmaceutical form:

Topical Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION:

2.1 Qualitative Declaration

Sr. No.	Name of Raw Materials	Specification
1	Betamethasone Dipropionate	BP
2	Salicylic acid	BP
3	PEG 400	USP
4	PEG 4000	USP
5	PEG 1500	USP
6	Lactic acid	BP
7	Sodium Lactate Solution	USP

BP – British Pharmacopeia.

USP – United States Pharmacopeia

2.2 Quantitative Declaration

Batch Size: 200 & 400 kg

BP – British Pharmacopeia.

USP – United States Pharmacopeia

Sr. No.	Name of Raw Materials	% Quantity	Standard batch quantity (200 kg)	Standard batch quantity (400 kg)
1	Betamethasone Dipropionate BP	0.067	135 gms	270 gms
2	Salicylic acid BP	3.07	6.150	12.300
3	PEG 400 USP	68.55	137.100	274.200
4	PEG 4000 USP	21.6	43.200	86.400
5	PEG 1500 USP	5.00	10.000	20.000
6	Lactic acid BP	0.037	0.075	0.150
7	Sodium Lactate Solution USP	1.68	3.375	6.750

3. PHARMACEUTICAL FORM:

Topical 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

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.

4.3 Method of administration: as directed by the physician.

4.4 Contraindications:

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

4.5 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-pituary-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.

4.6 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 Interaction with other medicinal products and other forms of interaction:

Tell your doctor of all nonprescription or prescription medication you may use, especially of: other skin medications. Do not start or stop any medicine without doctor or pharmacist approval.

4.8 Additional information on special populations

4.9 Pediatric population

None.

4.10 Fertility, Pregnancy and lactation:

4.10.1 General principles

4.10.2 Woman of childbearing potential / Contraception in males and females.

4.10.3 Pregnancy

4.10.4 Breastfeeding

4.10.5 Fertility

4.11 Effects on ability to drive and use machines:

None stated.

4.12 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.

4.13 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**.**

4.14 Preclinical safety data

No relevant data.

5. PHARMACEUTICAL PARTICULARS:

5.1 List of Excipients:

PEG 400, PEG 4000, PEG 1500, Lactic acid and Sodium Lactate Solution

5.2 Incompatibilities: None

5.3 Shelf life: 36 months from the date of manufacture.

5.4 Special precautions for storage: Do not store above 30°C.

5.5 Nature and contents of container:

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

5.6 Special precautions for disposal and other handling:

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

6. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS:

Marketing Authorization holder:

Centaur Pharmaceuticals Pvt. Ltd.

Manufacturing Site address:

Centaur Pharmaceuticals Pvt. Ltd.

Address: Plant: II, Plot No: 39, 40, 41 Tivim Industrial Estate, Karaswada, Mapusa Goa-403526

7. MARKETING AUTHORISATION NUMBER

528/(39)/MFG/DFDA/2004/5986

8. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

10/10/2005

9. DATE OF REVISION OF THE TEXT: July 2019

10. DOSIMETRY (IF APPLICABLE): NOT APPLICABLE.

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

NOT APPLICABLE