

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

DIPROSON CREAM

2. Qualitative and quantitative composition

Betamethasone Dipropionate equivalent to 0.05% betamethasone

Excipients with known effect

Chlorocresol

Cetostearyl alcohol

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

Diprosone is indicated for the treatment of Psoriasis, Eczema, Lichen simplex and planus, Anal and vulval pruritus, Otitis externa, Contact & Seborrhoeic dermatitis.

4.2 Posology and method of administration

Dosage:

While using diprosone cream apply a thin film to the affected skin areas once daily. In some cases, a twicedaily dosage may be necessary.

Route of Administration: For Topical use only

4.3 Contraindications

Diprosone is contraindicated in patients who are hypersensitive to Betamethasone Dipropionate.

4.4 Special warnings and precautions for use

Pregnancy

Diprosone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers

In nursing mothers systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

Pediatric Use

HPA axis (hypothalamic-pituitary-adrenal axis) suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

None has been reported on local application. Avoid using other topical medications.

4.6 Pregnancy and Lactation

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4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Diprosone skin preparations are generally well tolerated and side-effects are rare. The systemic absorption of betamethasone dipropionate 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.

The following local adverse reactions that have been reported with the use of Diprosone include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

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

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective National Regulatory Authorities.

4.9 Overdose

In children who were administered topical corticosteroids have been reported cases of suppression (reversible) of the HPA axis, Cushing's syndrome, linear retardation, delayed weight gain and intracranial hypertension. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Reports of

secondary infection and disorders of skin and subcutaneous tissues were related: burning, itching, dry skin, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, skin maceration, skin atrophy, striae and miliaria.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action

Diprosone is effective in the treatment of corticosteroid-responsive dermatoses primarily because of their anti-inflammatory, anti-pruritic, and vasoconstrictive actions. It acts as a local anti-inflammatory agent, acting on skin and mucous membrane. It suppresses release of several mediators of inflammation including Histamine, Prostaglandins, Leukotrienes.

Pharmacodynamic effects

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5.2 Pharmacokinetic properties

The degree of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. While topical corticosteroids can be absorbed from normal intact skin, dermal inflammation and / or other dermatological disease processes can increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. After dermal absorption, topical corticosteroids part similar to those of systemically administered corticosteroids pharmacokinetic pathways. Corticosteroids are bound to plasma proteins in varying degrees. They are metabolized primarily in the liver and excreted renally. Some topical corticosteroids and their metabolites undergo biliary excretion.

5.3 Preclinical safety data

None known.

6. Pharmaceutical Particulars

6.1 List of Excipients

Cetomacragol-1000 BP
Cetostearyl Alcohol BP
Methyl Hydroxybenzoate BP
Propyl Hydroxybenzoate BP
White soft Paraffin BP
Chlorocresol (PCMC) BP
Propylene Glycol BP

Sodium Dihydrogen Phosphate dihydrate BP
Purified water BP

6.2 Incompatibilities

None

6.3 Shelf-Life

36 months

6.4 Special Precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and Content of container

Diprosone cream is available in a Pack of 15gm tube.

Diprosone Cream 15 gm:

Printed Cylindrical Lami Tube with threaded neck and sealed nozzle.

Inside surface of the tube is lacquered with food grade epoxy resin. The nozzle of the tube is fitted with white plastic piercing cap.

6.6 Special precautions for disposal and other handling

None.

7. Marketing Authorization Holder

SHALINA HEALTHCARE DMCC

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

8. Marketing Authorization Number

H2022/CTD9351/20928

9. Date of first authorization/renewal of the authorization

19/11/2022

10. Date of revision of the text

19/11/2022