

DIPROSON CREAM
(Betamethasone Dipropionate Cream USP)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DIPROSON CREAM (Betamethasone Dipropionate Cream USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| Sr. No. | Ingredients | Specification | Label claim %w/v | Quantity /15 gm tube in mg | Function |
|---------|--------------------------------------------------------|---------------|------------------|----------------------------|----------------------------|
| 1. | Betamethasone Dipropionate equivalent to Betamethasone | USP | 0.05 % w/v | 9.63 ≅7.5 | Active Ingredient |
| 2. | Cetomacrogol 1000 | BP | --- | 450.0 | Cream Base |
| 3. | Cetostearyl Alcohol | BP | --- | 1200.0 | Cream Base |
| 4. | Methyl hydroxybenzoate | BP | --- | 22.5 | Antimicrobial Preservative |
| 5. | Propyl hydroxybenzoate | BP | --- | 7.5 | Antimicrobial Preservative |
| 6. | White soft Paraffin | BP | --- | 1500.0 | Emollient |
| 7. | Chlorocresol | BP | --- | 5.7 | Antimicrobial Preservative |
| 8. | Propylene Glycol | BP | --- | 750.0 | Solvent |
| 9. | Sodium Dihydrogen Phosphate | BP | --- | 3.75 | Buffering Agent |
| 10. | Purified Water | BP | --- | Q.S. to 15g | Vehicle |

* Betamethasone Dipropionate USP 1.286 g = 1.0 g of Betamethasone

Definitions:

USP: United State Pharmacopoeia

BP: British Pharmacopoeia

3. PHARMACEUTICAL FORM

Cream (Topical)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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4.2 Posology and method of administration

Dosage:

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

Route of Administration: For Topical use only

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Pregnancy - Diproson 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

Pregnancy - Diproson 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.

4.7 Adverse Reactions

None

4.8 Symptoms of Overdosage & Treatment

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,

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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

Diproson 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:

Diproson 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.

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.

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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 contents of container

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

Diproson 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 AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Country: UAE.

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Product is registered in DRC, Nigeria, Zambia, CAR & Ghana.