

EPIDERM CREAM

(Betamethasone Dipropionate, Gentamicin Sulphate, Tolnaftate and Iodochlorhydroxyquinoline Cream)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Epiderm Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Quantity per dosage unit in % w/w
Betamethasone Dipropionate USP	0.0643
Gentamicin Sulfate BP Equivalent to Gentamicin Base	0.10
Tolnaftate USP	1.00
Iodochlorhydroxyquinoline	1.00
Cetomacrogol 1000 BP	3.00
Cetostearyl Alcohol BP	8.00
Disodium Hydrogen Phosphate Dihydrate BP	0.012
Chlorocresol BP	0.10
White soft Paraffin (White Petroleum Jelly) BP	10.00
Propylene Glycol BP	5.00
Purified Water BP	q.s to 100.00

Note: BP: British Pharmacopoeia

IH: In-House Specification

USP: United States Pharmacopoeia

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Epiderm Cream is indicated for the treatment of following: Mixed bacterial and fungal infections, Tinea Infections of the skin (Ringworm), Otitis externa, Seborrhoeic dermatitis, Contact dermatitis, Eczemas, Psoriasis, Athlete's foot, Anal & vulval pruritis.

4.2 Posology and method of administration

Apply 2-3 times of Epiderm Cream a day to the affected area or as directed by physician.

4.3 Contraindications

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Epiderm Cream is contraindicated in patients who are hypersensitive to any of the component of the drug. It is also contraindicated in the treatment of herpes simplex, vaccina or varicella.

4.4 Special warnings and precautions for use

Paediatric Use: HPA 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

Epiderm Cream is not safe in pregnancy. Physician should be consulted before initiating therapy with Epiderm Cream for nursing mothers.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Epiderm Cream is generally well tolerated. Some of the rarely reported side effects are burning sensation, itching, irritation, dryness, folliculitis, acneform eruptions, hypopigmentation, maceration of the skin, secondary infection, skin atrophy etc.

4.9 Overdose

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in Secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic Treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological category: Epiderm Cream is a combination of anti-fungal, anti-bacterial & anti-inflammatory drugs, which provide synergetic action in treatment of mix bacterial & fungal infections.

Pharmacological action: Corticosteroids are thought to act by the induction of phospholipase A2 Inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the Biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes. Gentamicin is an aminoglycoside that binds to 30s and 50s ribosomal subunits of susceptible bacteria disrupting protein synthesis, thus rendering the bacterial cell membrane defective. Tolnaftate is an antifungal which inhibits growth of dermatophytes. Iodochlorhydroxyquinoline has antibacterial and antifungal activity.

5.2 Pharmacokinetic properties

Epiderm Cream: Absorption: Percutaneous absorption

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Elimination: Via urine.

5.3 Preclinical safety data

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol 1000 BP

Cetostearyl Alcohol BP

Chlorocresol BP

White Soft Paraffin BP

(Petroleum jelly)

Propylene Glycol BP

Paraffin Liquid Heavy BP

Disodium Hydrogen Phosphate Dihydrate BP

Purified Water BP

6.2 Incompatibilities

None.

6.3 Shelf life

36 months (3 Years).

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

5gm, 15gm & 30 gm Printed Lami tube;

Printed, Cylindrical 5gm, 15gm & 30 gm lami Tube with threaded neck and sealed nozzle.

The nozzle of the tube is fitted with white plastic piercing cap. Lami Tube shall be free from any printing & visual defects.

6.6 Special precautions for disposal and other handling

No special requirement

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC

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Jumeirah Lakes Towers Dubai-UAE.

8. DATE OF UPDATE OF TEXT

Nov 2019