

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC) - Enclosed

EPIDERM LOTION

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

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

EPIDERM LOTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. N	Ingredients	Specification	Label claim	Quantity per ml	Function
Active					
1.	Betamethasone Dipropionate	USP	0.0643 mg	0.643 mg	API
2.	Gentamicin Sulfate BP Equivalent to Gentamicin Base	BP	1.00 mg	1.00 mg	API
3.	Tolnaftate	USP	10.00 mg	10.00 mg	API
4.	Iodochlorhydroxyquinoline	IH	10.00 mg	10.00 mg	API
Excipients					
5.	Cetomacragol-1000	BP	---	7.00 mg	Emulsifying agent
6.	Cetostearyl Alcohol	BP	---	20.00 mg	Emulsifying agent
7.	Disodium Hydrogen Phosphate Dihydrate	BP	---	0.12 mg	Sequestering agent
8.	Chlorocresol	BP	1.00 mg	1.00 mg	Antimicrobial preservative
9.	White soft paraffin	BP	---	20.00 mg	Base
10	Propylene Glycol	BP	---	50.00 mg	Plasticizer
11	Heavy Liquid Paraffin	BP		5.00 mg	Emollient
12	Purified Water	BP	---	q.s. to 30 ml	Solvent

Definitions:

USP: United state Pharmacopoeia

BP: British Pharmacopoeia

IH: In House Specifications

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3. PHARMACEUTICAL FORM

Lotion (Topical)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Epiderm Lotion 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

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

Route of Administration: Topical

4.3 Contraindications

Epiderm Lotion 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.

Usage in Pregnancy & Lactation: Epiderm Lotion is not safe in pregnancy. Physician should be consulted before initiating therapy with Epiderm Lotion for nursing mothers.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction have been reported on local application with Epiderm Lotion. Avoid using other topical medications.

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4.6 Pregnancy and lactation

Usage in Pregnancy & Lactation: Epiderm Lotion is not safe in pregnancy. Physician should be consulted before initiating therapy with Epiderm Lotion for nursing mothers.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Epiderm Lotion 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

Pharmacotherapeutic group: Antifungal, anti-bacterial & anti-inflammatory drugs

ATC code:

Betamethasone Dipropionate: D07XC01

Gentamicin Sulfate: J01GB03

Tolnaftate: D01AE18

Iodochlorhydroxyquinoline: G01AC02

5.1 Pharmacodynamic properties

Epiderm Lotion is a combination of antifungal, anti-bacterial & anti-inflammatory drugs, which provide synergetic action in treatment of mix bacterial & fungal infections. Corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that

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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 Lotion: Absorption: Percutaneous absorption

Elimination: Via urine.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Cetomacragol-1000 BP, Cetostearyl Alcohol BP, Disodium Hydrogen Phosphate Dihydrate BP, Chlorocresol BP, White soft paraffin BP, Propylene Glycol BP, Heavy Liquid Paraffin 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

Epiderm Lotion is available in a Pack of 30ml bottle

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Golden pearlised Temper Evident HDPE Bottle with Pilfer proof cap. Pack of 30ml bottle. 1 such filled bottle is packed in a printed carton along with a leaflet.

6.6 Special precautions for disposal and other handling

No special requirement

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC,
30th Floor, Almas Towers,
Jumeirah Lakes Towers Dubai-UAE.

8. MARKETING AUTHORISATION NUMBER

Application for granting new registration certificate

9. DATE OF FIRST AUTHORISATION

Application for granting new registration certificate

10. DATE OF UPDATE OF TEXT

April 2021