

1.3 Product Information:

1.3.1 Summary of Product Characteristics (SmPC):

Enclosed.

1. NAME OF THE MEDICINAL PRODUCT

Product Name – SKINDID-E CREAM

Ketoconazole, Clobetasole Propionate & Neomycin Sulfate and

Vitamin E Cream Strength – 1.0% w/w, 0.5% w/w, 0.025% w/w

Pharmaceutical Form -Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole USP..... 1.0 % w/w

Clobetasole Propionate USP.....0.025 % w/w

Neomycin Sulfate USP..... 0.5 % w/w

Vitamin E

Cream Base.....q.s.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream

White Cream

4. Clinical particulars

4.1 Therapeutic indications

Ketoconazole has a potent antimycotic action against dermatophytes and yeasts. Ketoconazole cream acts rapidly on the pruritus, which is commonly seen in dermatophyte and yeast infections. This symptomatic improvement often occurs before the first signs of healing are observed.

Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of Clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

Neomycin is a rapidly bactericidal aminoglycoside antibiotic effective against Gram positive organisms including staphylococci and a wide range of Gram negative organisms. Strains of *Pseudomonas aeruginosa* are resistant to neomycin, as are fungi and viruses.

4.2 Posology and method of administration

Posology

Apply to the affected area once a day, depending on the severity of the infection, the cream may be applied on the affected area twice daily when necessary. Generally the duration of application depends on the type of infecting organism; Treat as bellows for die following:

Tinea Corporis 2 weeks; Tinea Cruris 2 weeks; Tinea Pedis 4 weeks; Tinea Manus 4 weeks.

Infection normally resistant to antifungal agents 4-6 weeks.

Method of administration

Topical administration only.

4.3 Contraindications

SKINDID E cream is contraindicated in patients with known hypersensitivity to any of its ingredients. SKINDID E is for topical use only and cannot be used for internal or ophthalmic use. Special precautions must be observed during use on pregnant women and children.

4.4 Special warnings and precautions for use

Warning: For external use only. Avoid contact eyes. Do not exceed prescribed dosage. Read carefully before using.

Precautions: Clinical studies of transcutaneous absorption conducted on animals and humans have proved that the reabsorption rate of ketoconazole cream is negligible; as such SKINDID E can be used inpregnancy under the supervision of a medical doctor. Application to the face or on large areas for longer periods of time than recommended in leaflet should be under a medical doctor's supervision.

4.5 Interaction with other medicinal products and other forms of interaction

SKINDID E as a topical cream does not interact with any other product.

4.6 Pregnancy and Lactation

There are no known risks associated with the use of SKINDID E cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

SKINDID E cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

SKINDID E is topical antifungal cream that is well tolerated and has little or no side effects when used properly. On occasion, irritation or burning sensation may occur during treatment. However it is unnecessary to discontinue treatment with SKINDID E. In severe or extreme cases you may contact the doctor.

4.9 Overdose

SKINDID E is well tolerated, no adverse effect has been observed in the event of overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Ketoconazole has a potent antimycotic action against dermatophytes and yeasts. Ketoconazole cream acts rapidly on the pruritus, which is commonly seen in dermatophyte and yeast infections. This symptomatic improvement often occurs before the first signs of healing are observed.

Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

Neomycin is a rapidly bactericidal aminoglycoside antibiotic effective against Gram positive organisms including staphylococci and a wide range of Gram negative organisms. Strains of *Pseudomonas aeruginosa* are resistant to neomycin, as are fungi and viruses.

5.2 Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole cream in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of ketoconazole cream was applied daily on 40 % of the body surface area, plasma levels of ketoconazole were detected in 5 infants, ranging from 32 to 133 ng/mL.

Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased.

Neomycin is either not absorbed or is absorbed only minimally through intact skin. Any neomycin which is absorbed will be rapidly excreted by the kidneys in an unchanged state.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol

Cetostearyl Alcohol

Macrogol cetostearyl ether

Methyl Paraben

Propyl Paraben

White Soft Paraffin

Monobasic Sodium phosphate

Dibasic hydrogen phosphate

Heavy Liquid Paraffin

Propylene Glycol

Disodium EDTA

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at temperature below 30°C in a dry place.

Do not freeze. Protect from light.

Keep the tube tightly closed after use.

6.5 Nature and contents of container

30 gm lami tube

6.6 Special precautions for disposal

No special requirements for disposal

7. MANUFACTURER

Baader Schulz Laboratories

Pharma Divison, Plot No J-6

OIDC, MG Udyog Nagar,

Dabhel, Nani Daman 396210

India