CEEZORAL CREAM

(Ketoconazole Cream)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

HYZORAL CREAM

(Ketoconazole Cream)

2. Qualitative and quantitative composition

Ketoconazole USP ….2. 00%w/w

Perfume IHS….. Q. S.

Cream Base ….. Q.S

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo.

4.2 Posology and method of administration

Posology

Ketoconazole cream is for use in adults.

For the treatment of tinea pedis (athlete's foot) and tinea cruris (dhobie itch) and candidal intertrigo (sweat rash).

Tinea cruris, candidal intertrigo and tinea pedis*:* It is recommended that Ketoconazole Cream be applied once or twice daily to cover the affected and immediate surrounding area.

The usual duration of treatment is tinea cruris 2-4 weeks, candidal intertrigo 2-4 weeks, tinea pedis 4-6 weeks.

Treatment should be continued, until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment.

Method of administration

Cutaneous use.

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4.3 Contraindications

Hypersensitivity to the Ketoconazole or to any of the excipients used.

4.4 Special warnings and precautions for use

Ketoconazole 2% cream is not for ophthalmic use.

To prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply Ketoconazole 2% cream in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

There are no known risks associated with the use of Ketoconazole 2% cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Adverse reactions reported for Ketoconazole include: Skin burning sensation, Hypersensitivity, Bullous eruption, Dermatitis contact, Rash, Skin exfoliation, Sticky skin. Application site erythema, Application site pruritus, Application site bleeding, Application site discomfort, Application site dryness, Application site inflammation, Application site irritation, Application site paraesthesia, Application Site reaction.

4.9 Overdose

Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.

In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives;

ATC code: D01 AC08.

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.

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.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. Pharmaceutical particulars

6.1 List of excipients

1. Macrogol cetostearyl ether BP
2. Cetostearyl Alcohol BP
3. Methyl Paraben BP
4. Propyl Paraben BP
5. White soft Paraffin BP
6. Chlorocresol BP
7. Propylene Glycol BP
8. Anhydrous Sodium Sulphite BP
9. Sodium Dihydrogen Phosphate Dihydrate BP
10. Perfume IHS
11. Purified Water BP / IHS

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a. Incompatibilities

Not applicable.

b. Shelf life

3 years

c. Special precautions for storage

Do not store above 30^0C. Protect from sunlight.

d. Nature and contents of container

30 g tube in a mono carton.

e. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Manufacturer Name

BAADER SCHULZ LABORATORIES PVT LTD

MAHATMA GANDHI UDYOG NAGAR

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8. Marketing Authority

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