SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

KETAZOL CREAM

COMPOSITION

Each gram of KETAZOL CREAM contains 20 mg ketoconazole

Excipients:

Cetyl alcohol, imidure, isopropyl myristate, polysorbate, propylene glycol, sodium sulphite, sorbitan stearate, stearyl alcohol, purified water.

Preservative: Imidurea 0,4 % *m/m*

CATEGORY AND CLASS

A 20.2.2: Antimicobial (Chemotherapeutic agents): Fungicides.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Ketoconazole is a synthetic imidazole dioxolane which has antimycotic activity against dermatophytes such as *Trichophyton spp*., *Epidermophyton floccosum* and *Microsporum spp*. and against yeasts.

Ketoconazole does not produce detectable blood levels after topical application.

INDICATIONS

KETAZOL CREAM is indicated for topical application in the treatment of dermatophyte infections of the skin: tinea corporis, tinea cruris, tinea manus and tinea pedis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Microsporum canis* and *Epidermophyton floccosum*, as well as in the treatment of cutaneous candidiasis and tinea (pityriasis) versicolor.

CONTRAINDICATIONS

KETAZOL CREAM is contraindicated in:

- Individuals who have shown hypersensitivity KETAZOL or any of its ingredients.
- KETAZOL CREAM crosses the placenta and should thus not be used by pregnant women.
- Safety in lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

Not for ophthalmic use.

Irritation may occur when KETAZOL CREAM is used immediately after prolonged treatment with topical corticosteroids.

Therefore, 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 KETAZOL CREAM in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2 to 3 weeks.

Effects on ability to drive and use machines

Not known.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

KETAZOL CREAM crosses the placenta and should thus not be used by pregnant women.

Safety in lactation has not been established (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Administration in adults:

KETAZOL CREAM should be applied to the affected area(s) once or twice daily.

Treatment should be continued for a sufficient period, at least until a few days after the disappearance of all symptoms.

The diagnosis and/or treatment should be reconsidered if no clinical improvement is noted after 4 weeks of therapy.

General measures with regard to hygiene should be observed to control sources of infection or re-infection.

The usual duration of treatment is: *tinea versicolor* (2 to 3 weeks), *yeast infections* (2 to 3 weeks), *tinea cruris* (2 to 4 weeks), *tinea corporis* (3 to 4 weeks) and *tinea pedis* (4 to 6 weeks).

Compliance with the full course is essential, as fungal infections may require prolonged therapy.

Administration in children:

Safety and efficacy have not been established in children.

SIDE EFFECTS

The most common side effects reported after application of KETAZOL CREAM include irritation, pruritis or a burning sensation.

Less commonly occurring effects include local skin phenomena such as contact dermatitis associated with the use of KETAZOL CREAM or one of its components, namely sodium sulphite or propylene glycol.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

Excessive topical applicaton may lead to erythema, oedema and a burning sensation.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A soft, smooth, homogenous, white, odourless cream with no evidence of creaming.

PRESENTATION

20 g packed in a collapsible aluminium tube with a membrane and sealed with a self-piercing white, high density polyethylene cap, and placed in a unit cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Do not refrigerate.

Prevent from freezing.

Keep the tube well closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

33/20.2.2/0503

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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