SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

TERBASPOR TOPICAL CREAM

COMPOSITION:

Active ingredient:

Each 1 g Terbaspor Topical Cream contains 10 mg terbinafine hydrochloride.

Excipients:

Benzyl alcohol, cetostearyl alcohol, cetyl palmitate 15, isopropyl myristate, polysorbate 60, sodium hydroxide, sorbitan stearate.

Contains preservative: benzyl alcohol 1,0 *% m/m*.

PHARMACOLOGICAL CLASSIFICATION:

A 20.2.2 Antimicrobial (chemotherapeutic) agents. Fungicides

PHARMACOLOGICAL ACTION:

Terbinafine is an allylamine with *in vitro* antifungal activity. At low concentrations, terbinafine is fungicidal against dermatophytes, moulds and certain fungi. The activity is fungicidal or fungistatic depending on the species.

Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane.

The enzyme squalene epoxidase is not linked to the cytochrome P450 system.

Less than 5 % of the dose is absorbed after topical application to humans.

INDICATIONS:

Adults and children over the age of 12 years:

Fungal infections of the skin caused by dermatophytes such as *Trichophyton* (eg. *T. rubrum*, *T. mentagrophytes*, *T. verrucosum*, *T. violaceum*) and *Epidermophyton floccosum*.

Yeast infections of the skin, principally those caused by *Candida albicans*.

Pityriasis (tinea) versicolor due to *Pityrosporum orbiculare* (also known as *Malassezia furfur*).

CONTRAINDICATIONS:

Hypersensitivity to terbinafine or to any of the excipients contained in the cream.

Use of TERBASPOR TOPICAL CREAM in children:

Safety in infants and children under 12 years has not been established.

Safety in pregnancy and lactation has not been established.

Terbinafine is excreted in breast milk.

WARNINGS AND SPECIAL PRECAUTIONS:

TERBASPOR TOPICAL CREAM is for external use only.

Contact with eyes should be avoided.

INTERACTIONS:

To date no drug interactions are known with topical use.

PREGNANCY AND LACTATION:

There is no clinical experience with **TERBASPOR TOPICAL CREAM** in pregnant women.

Terbinafine is excreted in breast milk and therefore mothers should not receive treatment with **TERBASPOR TOPICAL CREAM** whilst breastfeeding.

DOSAGE AND DIRECTIONS FOR USE:

TERBASPOR TOPICAL CREAM can be applied once or twice daily.

Cleanse and dry the affected areas thoroughly before treating with **TERBASPOR TOPICAL CREAM**. Apply the cream to the affected skin and surrounding area in a thin layer and rub in lightly. In the case of intertriginous infections (submammary, interdigital, intergluteal, inguinal) the application may be covered with gauze, especially at night.

Likely duration of treatment:

Tinea corporis, *cruris* (ringworm of the body, jock itch): once daily application for one week.

Tinea pedis (athlete's foot): once daily application for one week.

Cutaneous candidiasis (skin thrush): one week.

Pityriasis versicolor: two weeks.

Relief of symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after two weeks, the diagnosis should be verified.

Do not use for longer than one month.

Use of TERBASPOR TOPICAL CREAM in the elderly:

There is no evidence to suggest that elderly patients require different dosages or experience side effects different from those of younger patients.

SIDE EFFECTS:

Skin and subcutaneous tissue disorders:

Less frequent: Redness, itching, or stinging may occur at the site of application.

These symptoms must be distinguished from allergic reactions, which are rare but require discontinuation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Treatment is symptomatic and supportive.

IDENTIFICATION:

A white or almost white cream of homogenous appearance.

PRESENTATION:

Collapsible inside lacquered aluminium tubes of 7,5 and 15 g.

STORAGE INSTRUCTIONS:

Store in a cool place, at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

A39/20.2.2/0010

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

Sandoz SA (Pty) Ltd[1]

72 Steel Road

Spartan

Kempton Park

1619

South Africa

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[1]Company Reg. No: 1990/001979/07