**PROFESSIONAL INFORMATION**

**TERBI-CLEAR CREAM**

## SCHEDULING STATUS

**S1**

## 1. NAME OF THE MEDICINE

**TERBI-CLEAR CREAM**.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of TERBI-CLEAR CREAM contains 10 mg terbinafine hydrochloride.

Preservative: Benzyl alcohol: 1,5 % w/w.

For the full list of excipients see section 6.1.

## 3. PHARMACEUTICAL FORM

TERBI-CLEAR CREAM is a white or almost white cream.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

TERBI-CLEAR CREAM is indicated in adults and children over the age of 12 years for the treatment of the following skin infections:

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

Yeast infections of the skin primarily caused by *Candida albicans*.

Pityriasis (tinea) versicolor caused by *Pityrosporum orbiculare* (also known as *Malassezia furfur*).

## 4.2 Posology and method of administration

### Posology

Adults and children over the age of 12 years:

TERBI-CLEAR CREAM can be applied once or twice daily to the affected area(s).

***Special populations***

*Elderly*

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

***Paediatric population***

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

Its use can therefore not be recommended.

### Method of administration

TERBI-CLEAR CREAM is for external use only.

Cleanse and dry the affected area(s) thoroughly before applying TERBI-CLEAR CREAM. Apply a thin layer of the cream to the affected skin and surrounding area and rub in lightly. In the treatment of intertriginious infections (sub mammary, interdigital, intergluteal, inguinal), the application site may be covered with gauze, especially at night.

Duration and frequency of treatment:

Cutaneous candidiasis (skin thrush): To be applied for one week.

Pityriasis versicolor: To be applied for two weeks.

*Tinea corporis, cruris* (ring worm of the body, jock itch): To be applied once daily for one week.

*Tinea pedis* (athlete's foot): To be applied once daily for one week.

Relief of symptoms typically occurs within a few days of treatment initiation. If there

are no signs of improvement after two weeks, the diagnosis should be verified. Irregular use or premature discontinuation of treatment increases the risk of recurrence.

Do not use for longer than one month.

### 4.3 Contraindications

TERBI-CLEAR CREAM is contraindicated in patients with a known hypersensitivity to terbinafine, the active substance of TERBI-CLEAR CREAM or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

TERBI-CLEAR CREAM is for external use only.

Avoid contact with the eyes, as irritation may occur. In case of accidental contact with the eyes, rinse the eyes thoroughly with running water.

TERBI-CLEAR CREAM contains 15 mg benzyl alcohol in each gram of cream.

Benzyl alcohol may cause allergic reactions and mild local irritation.

TERBI-CLEAR CREAM contains cetyl alcohol and stearyl alcohol, which may cause local skin irritation (such as contact dermatitis).

*Paediatric population*

Safety in infants and children under the age of 12 years has not been established. The experience with topical terbinafine in children is also still limited and its use can therefore not be recommended.

### 4.5 Interaction with other medicines and other forms of interaction

There are no known interactions with other medicines and TERBI-CLEAR CREAM.

## 4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established; therefore, TERBI-CLEAR CREAM should not be used during pregnancy.

Breastfeeding

The use of TERBI-CLEAR CREAM during breastfeeding should be avoided, as terbinafine is excreted in breast milk.

Infants must not be allowed to come into contact with skin treated with TERBI-CLEAR CREAM, including the breast.

Fertility

There is no evidence that terbinafine has an effect on fertility.

## 4.7 Effects on ability to drive and use machines

If used as directed TERBI-CLEAR CREAM should not have an influence on the ability to drive and use machines.

## 4.8 Undesirable effects

Local symptoms such as pruritus, skin exfoliation, pain and irritation at the application site, pigmentation disorder, skin burning sensation, erythema and scabs may occur at the site of application.

These minor symptoms must be distinguished from hypersensitivity reactions such as widespread pruritus, rash, bullous eruptions and hives which are reported as sporadic cases but require discontinuation.

In case of accidental contact with the eyes TERBI-CLEAR CREAM may be irritating to the eyes.

In rare cases, the underlying fungal infection may be aggravated.

The following side effects are associated with TERBI-CLEAR CREAM:

*Immune system disorders:*

| | |
|---|---|
| Frequency unknown: | hypersensitivity. |

*Eye disorders:*

| | |
|---|---|
| Less frequent: | eye irritation. |

*Skin and subcutaneous tissue disorders:*

| | |
|---|---|
| Frequent: | skin exfoliation, pruritus. |
| Less frequent: | skin lesion, scab, skin disorder, pigmentation disorder, erythema, skin burning sensation, dry skin, contact dermatitis, eczema |
| Frequency unknown: | rash. |

General disorders and administration site conditions

| | |
|---|---|
| Less frequent: | pain and irritation (redness, itching and stinging) at the site of application, aggravated condition. |

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

### 4.9 Overdose

Overdosage with terbinafine is rare due to the low systemic absorption following topical administration. In the event of accidental ingestion, headache, nausea, epigastric pain and dizziness may be experienced.

Treatment of overdosage consists of eliminating the medicine by administering activated charcoal, as the primary method. Therapy should be symptomatic and supportive, if needed.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Category and Class: A. 20.2. 2 Antimicrobial (Chemotherapeutic) agents.

Fungicides.

Pharmacotherapeutic group: Antifungal for topical use.

ATC code: D01A E15.

Terbinafine is an allylamine antifungal with broad spectrum activity. Terbinafine acts by inhibiting the enzyme, squalene epoxidase, in the cell membrane of the fungus, thereby interfering with the biosynthesis of the fungal sterol. This leads to a deficiency of ergosterol and accumulation of squalene within the cell, leading to fungal cell death. Squalene epoxidase is not linked to the cytochrome P-450 system.

Low concentrations of terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. Terbinafine's activity against yeast is fungicidal and fungistatic against yeasts, depending of the species.

### 5.2 Pharmacokinetic properties

Following topical administration, less than 5 % of the dose is absorbed, therefore systemic exposure is low.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzyl alcohol

Cetyl alcohol

Cetyl palmitate

Isopropyl myristate

Polysorbate 60

Purified water

Sodium hydroxide

Sorbitan stearate

Stearyl alcohol

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

**KEEP OUT OF REACH OF CHILDREN.**

Store at or below 25 ºC.

Store in original packaging.

Do not use for more than 6 months after opening.

### 6.5 Nature and contents of container

TERBI-CLEAR CREAM is packed in 15 g and 30 g white collapsible aluminium tubes with a white cap with piercer.

### 6.6 Special precautions for disposal and other handling

None.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Activo Health (Pty) Ltd

Block B, Arena Office Park

272 West Avenue

Centurion

0157

## 8. REGISTRATION NUMBER(S)

*To be allocated.*

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

*To be allocated.*

## 10. DATE OF REVISION OF THE TEXT