PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

TERBI-CLEAR CREAM

Terbinafine hydrochloride

Read all of this leaflet carefully because it contains important information for you.

TERBI-CLEAR CREAM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use TERBI-CLEAR CREAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share TERBI-CLEAR CREAM with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve in 14 days.

What is in this leaflet

1. What TERBI-CLEAR CREAM is and what it is used for
2. What you need to know before you use TERBI-CLEAR CREAM
3. How to use TERBI-CLEAR CREAM
4. Possible side effects
5. How to store TERBI-CLEAR CREAM
6. Contents of the pack and other information

1. What TERBI-CLEAR CREAM is and what it is used for

TERBI-CLEAR CREAM is anti-fungal medicine.

It is use for the treatment of skin infections in adults and children over the age of 12 years. These include:

- Fungal injections (such as Athlete's foot, jock itch and ringworm).
- Yeast infections (for example, thrush).
- Pityriasis versicolor. This is a pale and patchy rash that occurs throughout the body.

2. What you need to know before you use TERBI-CLEAR CREAM

Do not use TERBI-CLEAR CREAM:

- if you are allergic (hypersensitive) to terbinafine or any of the other ingredients of TERBI-CLEAR CREAM (listed in section 6).

Warnings and precautions

TERBI-CLEAR CREAM is for external use only.

If you get TERBI-CLEAR CREAM in your eyes, immediately rinse your eyes thoroughly with clean water.

TERBI-CLEAR CREAM contains the inactive ingredients cetyl alcohol and stearyl alcohol. These ingredients may cause skin irritation at the site of application. Symptoms include redness, itching and stinging of the skin.

TERBI-CLEAR CREAM contains 15 mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

Children and adolescents

Safety in infants and children under the age of 12 years has not been established; its use can therefore not be recommended.

Other medicines and TERBI-CLEAR CREAM:

Always tell your healthcare provider if you are taking any other medicine.
(This includes complementary or traditional medicines).
It is unlikely that TERBI-CLEAR CREAM will interact with any medicines, because it is applied locally to the skin.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using TERBI-CLEAR CREAM.

Pregnancy

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

Breast-feeding

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.

Driving and using machines

TERBI-CLEAR CREAM acts locally where it is applied to the skin. If used as directed TERBI-CLEAR CREAM should not have an influence on the ability to drive and use machines.

3. How to use TERBI-CLEAR CREAM

Do not share medicines with any other person.

Always use TERBI-CLEAR CREAM exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

TERBI-CLEAR CREAM is for application to the skin only and should be applied once or twice a day to the affected area(s) in adults and children over the age of 12 years.

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

1. Clean and dry the affected area before applying TERBI-CLEAR CREAM.
2. Apply a thin layer of the cream to the affected area, including the skin surrounding this area.
3. Rub the cream in lightly.
4. If TERBI-CLEAR CREAM is applied to areas of the skin that may touch another skin area, you should cover the application site with gauze.

These areas include between the fingers and toes, under the breasts and in the buttocks or groin area.

Duration and frequency of treatment:

• Fungal injections:

- Athlete's foot: Apply TERBI-CLEAR CREAM once daily for 1 week.
- Jock itch and ringworm: Apply TERBI-CLEAR CREAM once daily for 1 week.

• Yeast infections (for example, thrush): Apply TERBI-CLEAR CREAM once or twice daily for 1 week.

• Pale and patchy rash throughout the body (pityriasis versicolor): Apply TERBI-CLEAR CREAM once or twice daily for 2 weeks.

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. Talk to your doctor.

Do not stop treatment early because your infection may return.

Do not use for longer than one (1) month.

If you use more TERBI-CLEAR CREAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Overdosage may occur if you accidentally swallow TERBI-CLEAR CREAM.

Signs and symptoms of overdosage may include headache, nausea, pain in the upper area of the stomach and dizziness.

If you forget to use TERBI-CLEAR CREAM

If you forgot to apply TERBI-CLEAR CREAM as per the suggested dosing intervals (see How to use TERBI-CLEAR CREAM), skip the missed dose and do not apply more cream but continue with the next dose at the next dosing interval.

4. Possible side effects

TERBI-CLEAR CREAM can have side effects.

Not all side effects reported for TERBI-CLEAR CREAM are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using TERBI-CLEAR CREAM, please consult your healthcare provider for advice.

If any of the following happens, stop using TERBI-CLEAR CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty breathing or swallowing, swelling of the mouth, face, lips, tongue or throat (severe allergic reaction).
- Severe itching of the skin, with a red rash or raised lumps, hives or blisters.

These are all very serious side effects. If you have them, you may have had a serious reaction to TERBI-CLEAR CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

• Itching and peeling of the skin.

<u>Less frequent side effects:</u>

• Eye irritation.

• Burning of the skin, contact dermatitis (inflammation of the skin when contact is made with an irritant), dry skin, eczema, redness of the skin, a change in skin colour, scabs, skin lesions and rash.

• Worsening of the condition, irritation (redness, itching and stinging) pain at the application site, and overall pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects 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.
By reporting side effects, you can help provide more information on the safety of TERBI-CLEAR CREAM.

5. How to store TERBI-CLEAR CREAM

Store all medicines out of reach of children**.**

Store at or below 25 ºC.

Store in the original packaging.

Do not use a tube of TERBI-CLEAR CREAM for more than 6 months after you first opened it, even if there is cream remaining in the tube.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TERBI-CLEAR CREAM contains

The active substance is terbinafine.

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

The other ingredients are benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan stearate and stearyl alcohol.

What TERBI-CLEAR CREAM looks like and contents of the pack

TERBI-CLEAR CREAM is a white or almost white cream which is packed in 15 g and 30 g white collapsible aluminium tubes 202 with a white cap with piercer.

Holder of Certificate of Registration and Manufacturer

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This leaflet was last revised in

To be confirmed.