SCHEDULING STATUS S1

TERBANE 10 mg (cream)

Terbinafine hydrochloride

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

- Keep this leaflet. You may need to read it again.
- Do not share TERBANE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What TERBANE is and what it is used for

2. What you need to know before you use TERBANE

3. How to use TERBANE

4. Possible side effects

5. How to store TERBANE

6. Contents of the pack and other information.

1. What TERBANE is and what it is used for

TERBANE cream contains the active ingredient terbinafine hydrochloride which is an antifungal. It kills fungi, which cause skin infections. TERBANE cream is used for the local treatment of fungal infections of the skin only.

2. What you need to know before you use TERBANE

Do not use TERBANE:

If you are hypersensitive (allergic) to terbinafine or any of the other ingredients of TERBANE (listed in section 6).

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 precautions

TERBANE cream is for external use only.

Contact with eyes should be avoided. If the cream gets in your eyes accidentally, rinse thoroughly with running water and tell your doctor immediately.

In the event of allergic reaction, the cream should be removed and the treatment interrupted.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents

TERBANE cream is not recommended for children under 12 years.

Other medicines and TERBANE

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

To date no medicine interactions are known with the topical use of TERBANE cream.

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 health care provider for advice before taking this medicine.

You should not use TERBANE if you are pregnant.

Terbinafine is excreted in breast milk and therefore mothers should not receive treatment with TERBANE whilst breastfeeding.

Driving and using machines

TERBANE should not affect your ability to drive or operate machines.

TERBANE contains benzyl alcohol and cetostearyl alcohol

TERBANE contains 10 mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation. TERBANE also contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3. How to use TERBANE

Do not share medicines prescribed for you with any other person.

Always use TERBANE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

TERBANE can be applied once or twice daily.

The recommended duration and frequency of treatment will depend upon the type and area of infection:

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.

Infections usually appear to improve within a few days of starting to use the cream. It is important that you use the cream regularly even if the infection has improved. If you see no improvement in your skin condition after two weeks, talk to your doctor.

Do not use for longer than one month.

Directions for use

- Cleanse and dry the affected areas thoroughly before treating with TERBANE.
- Apply the cream to the affected skin and surrounding area in a thin layer and rub in lightly.
- When used under the breasts, between the fingers, toes, buttocks or on the groin, the application may be covered with gauze, especially at night.

Use of TERBANE 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.

If you use more TERBANE than you should

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

Remove some of the cream if you apply more than a thin layer.

If you or someone else swallows the cream, go to your doctor or nearest hospital emergency department immediately. Take any remaining medicine and this leaflet with you if possible. Symptoms of accidental ingestion include headache, nausea (feeling sick), dizziness and stomach pain. If the cream gets in your eyes, rinse thoroughly with running water and tell your doctor immediately.

If you forget to use TERBANE

If you forget to use the cream, apply it as soon as you remember. If it is time for the next application, carry on as normal. It is important to try to remember to use the cream or you risk the infection returning.

If you stop using TERBANE

Do not stop using TERBANE before the recommended time, as the infection will be more likely to return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

TERBANE can have side effects.

Not all side effects reported for TERBANE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TERBANE, please consult your health care provider for advice.

If any of the following happens, stop using TERBANE 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 TERBANE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Skin peeling, itching.

Less frequent side effects:

- Redness, itching, or stinging may occur at the site of application.
- Pain and pain at the site of application.
- Worsening of symptoms and application site irritation.
- Skin lesions, scab, skin colour changes.
- Dry skin, contact dermatitis, eczema.
- Eye irritation.

The frequency of the following side effects are unknown:

- Rash.

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. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/%206.04_ARF1_v5.1_27Jan2020.pdf.

By reporting side effects, you can help provide more information on the safety of TERBANE.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store TERBANE

Store in a cool place, below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

Any unused medicines should be returned to your doctor, pharmacist or health care professional for disposal.

6. Contents of the pack and other information

What TERBANE cream contains

Each 1 g Terbane cream contains 10 mg terbinafine hydrochloride and 1,0 % *m/m* benzyl alcohol as preservative.

The other ingredients are benzyl alcohol, cetostearyl alcohol, cetyl palmitate 15, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan stearate.

What TERBANE looks like and contents of the pack

TERBANE cream is a white or almost white cream of homogenous appearance.

TERBANE cream is packed in collapsible inside lacquered aluminium tubes of 7,5 and 15 g with plastic screw caps.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

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Jukskei View

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Access to the corresponding Professional Information

Not applicable.

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