PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Terbane® 250 (tablets)

Terbinafine

Sugar free

Read all of this leaflet carefully before you start taking TERBANE 250

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TERBANE 250 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TERBANE 250 is and what it is used for

2. What you need to know before you take TERBANE 250

3. How to take TERBANE 250

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1. What TERBANE 250 is and what it is used for

Terbinafine, the active ingredient in TERBANE 250, is an antifungal medicine.

TERBANE 250 is used to treat a number of fungal infections of the skin and nails.

2. What you need to know before you take TERBANE 250

Do not take TERBANE 250:

- If you are hypersensitive (allergic) to terbinafine or any of the other ingredients of TERBANE 250 (listed in section 6)

- If you have or have had any liver problems
- If you are pregnant or breastfeeding

Warnings and precautions

Take special care with TERBANE 250:

- If you have any problems with your kidneys or liver
- If you have psoriasis
- If you have a condition called systemic lupus erythematosus (SLE)

You should have blood tests before and during treatment with TERBANE 250 to monitor your liver function.

Other medicines and TERBANE 250

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

Tell your doctor if you are taking any of the following:

- Cimetidine – used for gastric problems such as indigestion or stomach ulcers
- Medicines used to treat fungal infections (e.g. fluconazole, ketoconazole)
- Medicines used to treat heart problems (e.g. amiodarone)
- Beta-blockers or anti-arrhythmics used to control the rate and rhythm of the heart
- Rifampicin – an antibiotic used to treat different types of bacterial infections, including TB
- Caffeine
- Medicines used for the treatment of depression, including tricyclic antidepressants, SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)
- Medicines used to treat cough (e.g. dextromethorphan)
- Oral contraceptives (the pill), as irregular periods and breakthrough bleeding may occur in some female patients
- Tolbutamine – used for the treatment of diabetes
- Terfenadine – an antihistamine used for the treatment of allergies

- Ciclosporin - a medicine used to control your body's immune system in order to prevent rejection of transplanted organs
- Warfarin - a medicine used to thin your blood

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.

Do not take TERBANE 250 if you are pregnant or whilst breastfeeding.

Driving and using machines

Some people have reported feeling dizzy while they are taking TERBANE 250. If you feel like this, you should not drive or operate machinery.

3. How to take TERBANE 250

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

Always take TERBANE 250 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults, including the elderly, is 250 mg once a day.

- The treatment duration for skin infections is usually 2 to 6 weeks, depending on the infection.
- For nail infections, treatment usually lasts for between 6 weeks and 3 months, although some patients with toenail infections may need to be treated for 6 months or longer.
- If your kidneys or liver are not working very well, you should not take TERBANE 250.
- Take the tablets orally with a glass of water. They should preferably be taken at the same time each day and can be taken on an empty stomach or after a meal.

If you take more TERBANE 250 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Symptoms caused by an overdose include headache, nausea, stomach pain and dizziness.

If you forget to take TERBANE 250

If you miss a dose, take your normal dose when it is next due. Do not take a double dose to make up for forgotten doses.

If you stop taking TERBANE 250

Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

4. Possible side effects

TERBANE 250 can have side effects.

Not all side effects reported for TERBANE 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TERBANE 250, please consult your health care provider for advice.

If any of the following happens, stop taking TERBANE 250 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Yellowing of your skin or eyes. Unusually dark urine or pale faeces, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (this may indicate liver problems), increase in liver enzymes which may be noted on a blood test result
- Severe skin reactions including rash, light sensitivity or blistering (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, toxic skin eruption, dermatitis exfoliative, dermatitis bullous)
- Weakness, unusual bleeding, bruising, abnormal pale skin, unusual tiredness, or weakness or breathlessness on exertion or frequent infections (this may be a sign of blood disorders)
- Difficulty breathing, dizziness, swelling mainly of the face and throat, flushing, abdominal pain and cramping, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish spots under the skin surface (signs of blood vessel inflammation)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation)

- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible signs of muscle breakdown)

These are all very serious side effects. If you have them, you may have had a serious reaction to TERBANE 250. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Loss of appetite
- Headache
- Taste loss and taste disturbance (this usually disappears when you stop taking TERBANE 250)
- Feeling bloated or full
- Indigestion
- Nausea
- Stomach ache
- Diarrhoea
- Itching, rash or swelling
- Pains in the muscles and joints

Less frequent side effects:

- Decrease in the number of some blood cells (observed through blood tests, or you may notice that you seem to bleed or bruise more easily than normal, or you may catch infections easily and these might be more severe than usual)
- Onset or worsening of a condition called lupus (a long-term illness with symptoms including skin rash and pain in the muscles and joints)
- Numbness or tingling of the skin
- Dizziness
- Vertigo
- Hair loss
- Psoriasis-like skin eruptions, or worsening of any psoriasis including a rash or eruption of small pus containing blisters

- General feeling of being unwell
- Decrease in weight due to taste disturbances

The frequency of the following side effects are unknown:

- Anxiety or symptoms of depression
- Disorders of sense of smell, which may be permanent
- Reduced or blurred vision
- Impaired hearing, hissing and/or ringing in the ears
- A red, scaly rash with bumps under the skin and blisters (acute generalised exanthemous pustulosis)
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- Flu-like symptoms
- Fever
- Feeling tired
- Increase in blood of a muscle enzyme called creatine phosphokinase (may be determined with a blood test)

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://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TERBANE 250.

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

5. How to store TERBANE 250

Store at or below 25 °C. Protect from light.

Keep the blisters in the carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information

What TERBANE 250 contains

The active substance is terbinafine.

The other ingredients are colloidal anhydrous silica, hypromellose, magnesium stearate, potato starch and sodium starch glycolate.

What TERBANE 250 looks like and contents of the pack

White or almost white, round, scored, convex tablet, coded TER 250 on one side.

TERBANE 250 is packed in:

Transparent or white opaque PVC form foil with white or metallic aluminium lidding foil blister packs of 14 tablets.

OR

White, round polyethylene (PE-HD) containers with white, round polyethylene tamper evident screw caps containing 14 tablets.

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

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2090

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Access to the corresponding Professional Information

Not applicable.

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