

Terbinafine Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Terbinafine Sandoz?

Terbinafine Sandoz contains active ingredient Terbinafine hydrochloride. Terbinafine Sandoz is used to treat ringworm (tinea) infections occurring in groin, body, feet and soles. It is also used to treat fungal infection of finger and toenails.

For more information, see Section [1. Why am I using Terbinafine Sandoz?](#) in the full CMI.

2. What should I know before I use Terbinafine Sandoz?

Do not use if you have ever had an allergic reaction to terbinafine hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Terbinafine Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Terbinafine Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Terbinafine Sandoz?

- Your doctor will advise you on the appropriate dose.
- For skin infections: take 250 mg Terbinafine Sandoz once a day
- For fungal infection of finger and toenails: take 250 mg Terbinafine Sandoz once a day
- If your fungal infection does not improve. Your doctor will review and determine if an alternative antifungal therapy is needed.

More instructions can be found in Section [4. How do I use Terbinafine Sandoz?](#) in the full CMI.

5. What should I know while using Terbinafine Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or specialist you visit that you are using Terbinafine Sandoz.• Tell your doctor immediately if you develop any signs of an allergic reaction.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not use Terbinafine Sandoz in children.
Driving or using machines	<ul style="list-style-type: none">• Terbinafine Sandoz may cause dizziness in some people. Avoid driving vehicles or using machines if you are dizzy.• Be careful before you drive or use any machines or tools until you know how Terbinafine Sandoz affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Protect from light.

For more information, see Section [5. What should I know while using Terbinafine Sandoz?](#) in the full CMI.

6. Are there any side effects?

Common side effects include low appetite, headache, dizziness, weakness, vomiting, rash, hives, feeling sick, yellowing of the skin and eyes, light-coloured stools, dark coloured urine, indigestion.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Terbinafine Sandoz®

Active ingredient(s): *Terbinafine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Terbinafine Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Terbinafine Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Terbinafine Sandoz?](#)
- [2. What should I know before I use Terbinafine Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Terbinafine Sandoz?](#)
- [5. What should I know while using Terbinafine Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Terbinafine Sandoz?

Terbinafine Sandoz contains the active ingredient **terbinafine hydrochloride**. Terbinafine Sandoz belongs to a group of medications called antifungals.

Terbinafine Sandoz is used to treat ringworm (tinea) infections occurring in groin, body, feet (athlete's foot) and soles. It is also used to treat fungal infection of finger and toenails (Onychomycosis). These infections are caused by a group of fungi called dermatophytes. Terbinafine Sandoz help to kill these dermatophytes.

2. What should I know before I use Terbinafine Sandoz?

Warnings

Do not use Terbinafine Sandoz:

- If you are allergic to terbinafine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of allergic reaction include swelling of the face, lips, tongue or other parts of the body, difficulty in breathing, redness, itching or rash on the skin, rash, fever.

Check with your doctor if you:

- have any other medical conditions such as liver problems or any symptoms such as feeling sick, loss of appetite, weakness, vomiting, pain in right upper part of tummy or yellowing of skin or eyes, dark urine or pale stools.
- suffer from any kidney diseases.
- take any medicines for any other condition.

- have any skin diseases like Psoriasis (skin problem that causes a rash with itchy, scaly patches), rash or any other serious skin reactions (e.g. Stevens-Johnson syndrome, a serious disorder of the skin with symptoms such as blisters, weakness, fever or toxic epidermal necrolysis, severe skin problem having symptoms of blistering and peeling of skin)
- have any problems related to your blood (e.g. unusual bleeding, bruising or frequent infections)
- have or develop unexplained bleeding or blot clots.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Terbinafine hydrochloride is not recommended during pregnancy. Your doctor will advise you regarding the possible risks and benefits of using Terbinafine Sandoz during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use Terbinafine Sandoz during breastfeeding as Terbinafine hydrochloride passes in breast milk.

Laboratory tests

- Your doctor might do routine blood tests, liver function test before and during treatment with Terbinafine Sandoz.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Terbinafine Sandoz and affect how it works.

Tell your doctor or pharmacist if you take any of the following:

- Warfarin, a drug used to prevent blood clots
- Oral contraceptives (birth control pills)
- Medicines used to treat heart problems (e.g. metoprolol)
- Caffeine
- Drugs used to treat depression and other mental problems (e.g. tricyclic antidepressants: desipramine, selective serotonin reuptake inhibitors (SSRIs), antiarrhythmics Class 1A, 1B, and IC, and monoamine oxidase inhibitors (MAOIs) Type B)

- Ciclosporin, a medicine used to treat certain problems with the immune system
- Drugs used for treatment of cough e.g. dextromethorphan

Medicines that may increase the effect of Terbinafine Sandoz:

- Cimetidine or other similar medicines used to treat stomach problems
- Other antifungal medicines such as fluconazole, ketoconazole

Medicines that may reduce the effect of Terbinafine Sandoz:

- Rifampicin or other similar antibiotics used to treat infections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Terbinafine Sandoz.

4. How do I use Terbinafine Sandoz?

How much to take

- Follow the instructions provided and use Terbinafine Sandoz until your doctor tells you to stop.
- For skin infections: take 250 mg Terbinafine Sandoz once a day
- For fungal infection of finger and toenails (onychomycosis): take 250 mg Terbinafine Sandoz once a day

Duration of Treatment:

- Your doctor will advise you regarding the duration of treatment.
- Generally, for skin infections of toes: 2 to 6 weeks
- For fungal infection of body or the groin: 2 to 4 weeks
- For fungal infection of finger and toenails (onychomycosis): 6 weeks - 3 months.
- For infection in the big toe, treatment may take up to 6 months.
- **If you do not understand your dose, consult your doctor or pharmacist.**

If your fungal infection does not improve. Your doctor will review and determine if an alternative antifungal therapy is needed.

When to take Terbinafine Sandoz

- Take Terbinafine Sandoz orally at about the same time each day.

How to take Terbinafine Sandoz

- Take Terbinafine Sandoz orally with a full glass of water. If you notice that the Terbinafine Sandoz upsets your stomach, try taking it immediately after a light meal.

If you forget to use Terbinafine Sandoz

Terbinafine Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time,

take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Terbinafine Sandoz

If you think that you have used too much Terbinafine Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Terbinafine Sandoz?

Things you should do

Keep the infected areas dry and cool and change clothing which is in direct contact with the infected areas every day.

Call your doctor straight away if you:

- develop any signs of allergic reaction.
- become pregnant or if you are breast feeding while using Terbinafine Sandoz.
- have any problems with your liver, kidney or blood
- experience multiple blood clots.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Terbinafine Sandoz.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use Terbinafine Sandoz in children.
- Do not give Terbinafine Sandoz to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Terbinafine Sandoz affects you.

Terbinafine hydrochloride may cause dizziness in some people. Avoid driving vehicles or using machines if you are dizzy.

Looking after your medicine

- Store below 25°C.
- Protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General problems:</p> <ul style="list-style-type: none"> • Low appetite • Joint pain • Muscle pain or weakness, not caused by exercise • Headache • Dizziness • Tiredness • Blurred vision • Vision problems • Fever, chills, body pain, dry cough <p>Skin problems:</p> <ul style="list-style-type: none"> • Hives • Rash • Itching • Redness of the skin <p>Tummy problems:</p> <ul style="list-style-type: none"> • Feeling sick • Vomiting • Uncomfortable feeling in tummy • Excessive feeling of gas in the tummy • Cramps or pain in tummy • Diarrhoea • Indigestion • Excessive burping • Swelling of your belly. <p>Other problems:</p> <ul style="list-style-type: none"> • Anxiety • Depression 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>General problems:</p> <ul style="list-style-type: none"> • Allergic reaction such as swelling of the face, lips, tongue or other parts of the body, difficulty in breathing, redness, itching or rash on the skin, rash, fever. • Problems with your blood vessels having symptoms like fever, weight loss, tiredness, rash. <p>Tummy problems:</p> <ul style="list-style-type: none"> • Pain in tummy, vomiting, blood in the stools (swelling of the stomach lining) • Yellowing of the skin and eyes, feeling sick, light-coloured stools, dark colour urine <p>Skin problems:</p> <ul style="list-style-type: none"> • Itchy rash, fever, joint pains • Fever, red rash, painful red areas, blisters, peeling of layers of skin (may indicate serious skin reaction) <p>Abnormal blood tests:</p> <ul style="list-style-type: none"> • Dark-coloured urine, weakness • Weakness, feeling sick, swelling on arms, legs, or face • Yellowing of skin or eyes, loss of appetite, vomiting • Unexplained weakness, tummy problems, • Weakness, shortness of breath dizziness or lightheadedness pale skin, headaches • Fever and chills, mouth sores, sore throat • Chest pain, weakness, fever, muscle stiffness <p>Other problems:</p> <ul style="list-style-type: none"> • Hearing problems • Partial loss of hearing • Taste disturbance • Loss of taste • Decreased ability to smell or detect odours • Loss of the sense of smell 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Terbinafine Sandoz contains

Active ingredient (main ingredient)	Terbinafine hydrochloride
Other ingredients (inactive ingredients)	Sodium starch glycollate, hypromellose, colloidal anhydrous silica, potato starch, magnesium stearate
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What Terbinafine Sandoz looks like

Terbinafine Sandoz 250 mg - white or almost white, round, scored on both sides, convex tablet, coded 'TER 250' on one side (AUST R 101685).

Available in blister packs of 42 tablets.

Who distributes Terbinafine Sandoz

Terbinafine Sandoz is supplied in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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