

Terbinafine Sandoz®

terbinafine hydrochloride tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Terbinafine Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT TERBINAFINE SANDOZ IS USED FOR

Terbinafine Sandoz is used to treat infections caused by dermatophytes, a type of fungi, including the following:

- fungal infections of the finger nails and toe nails
- tinea (ringworm) infections of the groin and body
- tinea infections of the feet ("athlete's foot").

It contains the active ingredient terbinafine.

Terbinafine belongs to a group of medicines called antifungal agents of the allylamine type.

It works by killing the fungi which cause the infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

BEFORE YOU TAKE TERBINAFINE SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- terbinafine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- problems with your kidneys
- a problem with your liver. This medicine is not recommended if you currently have a liver problem because it may make the problem worse. If you have had a liver problem in the past

but your liver is now functioning normally, your doctor may prescribe Terbinafine Sandoz, but may want to check your liver function before and during treatment with this medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- skin problems such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of serious skin reactions), rash due to high level of a specific type of white blood cells (eosinophilia)
- blood disorders or weakness, unusual bleeding, bruising or frequent infections
- thickened patches of red/silver skin (psoriasis) or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus).

Tell your doctor if you are pregnant or plan to become pregnant.

There is no experience with use of this medicine during pregnancy. If your doctor thinks it is necessary

for you to take it, he/she will discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

Breastfeeding is not recommended since terbinafine, the active ingredient in Terbinafine Sandoz, passes into the breast milk and might affect your baby.

If you have not told your doctor about any of the above, tell him/her before you start taking Terbinafine Sandoz.

Taking other medicines

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

Some medicines and Terbinafine Sandoz may interfere with each other. These include:

- some medicines used to treat depression and other mental disorders, including obsessive-compulsive disorders and panic attacks (e.g. some antidepressants such as tricyclic antidepressants, selective serotonin reuptake inhibitors including class 1A, 1B and 1C, monoamine oxidase inhibitors Type B, desipramine)
- some medicines for Parkinson's disease
- beta-blocker medicines used to treat high blood pressure, heart problems and migraines (e.g. metoprolol)
- some antiarrhythmic medicines used to treat irregular heart beat (e.g. amiodarone)
- some medicines to treat stomach ulcers (e.g. cimetidine)
- some antibiotics (e.g. rifampicin)
- caffeine
- warfarin, a medicine used to prevent blood clots
- cyclosporin, a medicine used to help prevent organ transplant

rejection or to treat certain problems with the immune system

- oral contraceptives (birth control pills). Problems with your period, such as bleeding between periods, may occur while you are taking Terbinafine Sandoz.
- some medicines used to treat fungal infections (e.g. fluconazole, ketoconazole)
- some medicines used to treat cough (e.g. dextromethorphan).

These medicines may be affected by Terbinafine Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE TERBINAFINE SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The usual dose of Terbinafine Sandoz is one 250 mg tablet each day.

If you have kidney problems, the dose may be reduced to one-half a tablet each day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Terbinafine Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

If your stomach is upset after taking your medicine, try taking it immediately after a light meal.

If you need to break the tablet, hold it with both hands and snap along break line.

When to take Terbinafine Sandoz

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Terbinafine Sandoz

The length of your treatment can vary and depends on several parameters such as the type of infection you have, what part of the body is affected and how you respond to the treatment.

Fungal skin infections (tinea):

If you have a tinea infection of the feet (athlete's foot), the usual duration of treatment is 2 to 6 weeks.

If you have a tinea infection of the body or groin, the usual duration of treatment is 2 to 4 weeks.

However, the symptoms of infection may continue for several weeks after the fungi have been killed.

Fungal nail infections:

As fungal nail infections usually take longer to heal than fungal skin infections, you will usually take the tablets for 6 weeks to 3 months. The length of your treatment depends on which of your nails is infected and how fast they grow. In some cases

you may need to take the tablets for up to 6 months.

It may take several months after you stop taking Terbinafine Sandoz for your nail to look completely normal. That is because the infected part of the nail has to grow out and be replaced by a healthy nail.

If you forget to take it

Take your dose as soon as you remember, and continue to take 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 that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Terbinafine Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include headache, nausea (feeling sick), stomach pain and dizziness.

WHILE YOU ARE TAKING TERBINAFINE SANDOZ

Things you must do

Make sure to take your dose every day and continue taking it until your doctor tells you to stop.

This will ensure that all of the infection is gone and will lessen the chance of the infection coming back once you stop taking this medicine.

Make sure to have any blood tests done that are ordered by your doctor.

Any side effects on your liver, kidneys or blood can be detected by blood tests.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Terbinafine Sandoz.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Your doctor can discuss with you the risks and benefits of taking it during pregnancy.

Tell your doctor immediately if you notice any of the following:

- fever
- sore throat
- mouth ulcers
- "flu-like" symptoms (chills, aching joints, swollen glands, lack of energy)
- any other signs of infection, apart from the fungal infection you are being treated for.

Things you must not do

Do not take Terbinafine Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Terbinafine Sandoz affects you.

This medicine may cause tiredness, sleepiness, dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Make sure to keep the infected areas dry and cool and change clothing that is in direct contact with the infected areas every day.

This will help to clear up the infection and make sure that it does not return.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Terbinafine Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea (feeling sick) or vomiting
- upset stomach (heartburn, cramps, wind, belching)
- loss of appetite
- diarrhoea
- aching joints or muscles
- headache
- light headedness

- tiredness, sleepiness
- skin rash due to high level of a specific type of white blood cells
- psoriasis (thickened patches of red skin, often with silvery scales)
- other skin problems
- loss of or change in sense of taste which usually returns to normal within several weeks after stopping Terbinafine Sandoz treatment
- blurred vision, decreased sharpness of vision
- hair loss
- tingling or numbness
- decreased physical sensitivity
- smell disorders or loss of smell
- anxiety (with symptoms such as sleep disturbances, fatigue, loss of energy or diminished ability to think or concentrate) and depressive symptoms (e.g. depressed mood) due to taste disturbances
- decreased hearing, impaired hearing and/or perception of noises in the absence of sound (e.g. hissing, ringing) in ears
- increased skin sensitivity to light.

If you notice any of the following, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- signs of a severe allergic reaction such as swelling of the face, lips, tongue, throat or other part of the body; shortness of breath, wheezing or troubled breathing; dizziness, redness, itching or rash on the skin; flushing, crampy abdominal pain, loss of consciousness; joint pain, stiffness, rash, fever or swollen/enlarged lymph nodes
- possible signs of a serious liver problem such as persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, yellowing

of the skin and/or eyes, dark urine or pale bowel motions

- possible signs of serious skin reactions such as painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals. These signs may be accompanied by fever and chills, aching muscles and feeling generally unwell.
- possible signs of a blood problem such as constant "flu-like" symptoms (fever, sore throat, mouth ulcers, chills, swollen glands, lack of energy)
- possible signs of diseases that affect certain types of blood cells: unusual bleeding or bruising
- possible signs of a disease that affects the level of red blood cells including abnormal pale skin, mucosal lining or nail beds, unusual tiredness or weakness or breathlessness on exertion
- possible signs of blood vessel inflammation: rash, fever, itching, tiredness or if you notice appearance of purplish-red spots under the skin surface
- possible signs of pancreas inflammation: severe upper stomach pain with radiation to the back
- possible signs of muscle necrosis: unexplained muscle weakness and pain or dark (red-brown) urine.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

Other side effects not listed above may also occur in some people.

AFTER TAKING TERBINAFINE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Terbinafine Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your medicine where it is protected from light.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Terbinafine Sandoz comes in one strength:

Terbinafine Sandoz 250mg - white or almost white, round, scored, convex tablet, coded 'TER 250' on one side.

Available in blister packs of 42 tablets.

Ingredients

Active ingredient:

- Terbinafine Sandoz 250mg - 250mg terbinafine as terbinafine hydrochloride.

Inactive ingredients:

- sodium starch glycollate
- hypromellose
- colloidal anhydrous silica
- potato starch
- magnesium stearate.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
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(blisters)