

TERBINAFINE GH

terbinafine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **TERBINAFINE GH**.

It does not contain all the available information about **TERBINAFINE GH**.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **TERBINAFINE GH** against the benefits it is expected to 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 GH is used for

TERBINAFINE GH contains terbinafine (as hydrochloride).

TERBINAFINE GH is used to treat:

- fungal infections of the finger nails and toe nails

- tinea (ringworm) infections of the groin and body
- tinea infections of the feet, commonly called "athlete's foot"

These infections are caused by a group of fungi called dermatophytes.

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.

TERBINAFINE GH terbinafine tablets are only available with a doctor's prescription. This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

How does TERBINAFINE GH work?

Terbinafine works by killing the dermatophytes.

Before you take TERBINAFINE GH

When not to take it

Do not take TERBINAFINE GH if you have ever had an allergic reaction to terbinafine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet, or to any other medicines, foods, preservatives or dyes.

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.

If you have any problems with your kidneys, have or ever had a problem with your liver, do not take TERBINAFINE GH until you have discussed this problem with your doctor.

This medicine is not recommended if you currently have a liver problem because it may make the problem worse.

If you had a liver problem in the past but your liver is functioning normally now, your doctor may prescribe **TERBINAFINE GH** but may want to check your liver function before and during treatment with this medicine. Your doctor might take blood tests to monitor your liver function. In case of abnormal test results he or she may ask you to stop taking **TERBINAFINE GH**.

Do not take TERBINAFINE GH after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

Before you start to take it

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

There is no experience with use of **TERBINAFINE GH** during pregnancy. If your doctor thinks it is necessary for you to take it, he/she will discuss with you the benefits and risks involved.

Tell your doctor if you are breast-feeding.

Breast-feeding is not recommended since terbinafine, the active ingredient in **TERBINAFINE GH**,

passes into breast milk. There is a possibility that your baby could be affected.

Tell your doctor if you have any 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)

Tell your doctor if you have any blood disorders.

Or experience weakness, unusual bleeding, bruising or frequent infections.

Tell your doctor if you have or experience thickened patches of red/silver skin (psoriasis).

Or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus).

If you are not sure whether you should start taking TERBINAFINE GH tablets, talk to your doctor or pharmacist.

Taking other medicines

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

Some medicines and terbinafine 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 inhibitor including class 1A, 1B and 1C, monoamine oxidase inhibitors Type B, desipramine)
- some medicines for Parkinson's disease
- some medicines used to treat heart problems, high blood pressure and migraines (e.g. metoprolol), and irregular heart beats

- some medicines used to treat stomach ulcers, e.g. cimetidine
- some antibiotics used to treat infectious diseases, e.g. rifampicin
- caffeine
- oral contraceptives (birth control pills). You may have problems, such as bleeding between periods, while you are taking terbinafine.
- 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

You may need to take 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 to avoid while taking **TERBINAFINE GH**.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take TERBINAFINE GH

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

These directions may differ from the information contained in this leaflet.

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

How much to take

Follow your doctor's instructions on how many **TERBINAFINE GH** tablets to take.

The usual dose of **TERBINAFINE GH** is one tablet (250 mg) each day. If you have kidney problems,

the dose may be reduced to one-half of a tablet each day.

If you suffer from any kidney problem, your dose will be lower than other adults and it will be decided by your doctor.

How to take it

Take the tablet with a full glass of water. If you find that TERBINAFINE GH upsets your stomach, try taking it immediately after a light meal.

When to take it

Take the tablet at about the same time each day.

Taking your tablet 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 it for

The length of your treatment will depend on the type of infection you have, what part of the body is affected and how well you respond to treatment.

Fungal skin infections (tinea)

If you have a tinea infection of the feet (athlete's foot), you will usually take the tablets for 2 to 6 weeks.

If you have a tinea infection of the body or groin, you will usually take the tablets for 2 to 4 weeks.

The signs and symptoms of infection may last for several weeks after the fungi (dermatophytes) have been killed.

Fungal nail infections

Fungal nail infections usually take longer to heal than fungal skin infections. You will usually take the tablets for anywhere from 6 weeks to 3 months. But if you have a nail infection of the big toe or your nails grow very slowly, you may need to take the tablets for up to 6 months.

It may take several months after you stop taking **TERBINAFINE GH** for your nail to look completely normal. That is because the deformed part of the nail has to

grow out and be replaced by a healthy nail.

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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 TERBINAFAINE GH. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Please keep these phone numbers handy.

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

While you are taking TERBINAFAINE GH

Things you must do

Make sure to take your tablet 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.

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

If you become pregnant while taking TERBINAFAINE GH, tell your doctor immediately.

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

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

Tell any other doctor, dentist or pharmacist who treats you that you are taking TERBINAFAINE GH.

If you forget to take it

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take the next dose when you are meant to.

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

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

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

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

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking TERBINAFAINE GH until you know how it affects you.

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

Be careful 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 TERBINAFAINE GH, even if you do not think it is connected with the medicine.

All medicines can have side effects.

Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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; redness, itching or rash on the skin; flushing, crampy abdominal pain, loss of consciousness; joint pain, stiffness, rash, fever or swollen/enlarged lymph nodes
- signs of a possible 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
- signs of a serious skin reaction 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
- signs of a possible blood problem such as constant "flu-like" symptoms (fever, sore throat, mouth ulcers, chills, swollen glands, lack of energy)
- chest pain
- 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 are serious side effects that need medical attention. Serious side effects are rare.

Tell your doctor 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
- loss of or change in sense of taste, which usually returns to normal within several weeks of stopping **TERBINAFINE GH**
- blurred vision, decreased sharpness of vision

- psoriasis (thickened patches of red skin, often with silvery scales)
- other skin problems
- 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.

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

Some people may have other side effects not yet known or mentioned in this leaflet.

How to store TERBINAFINE GH

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool, dry place below 25°C and protected from light.
- Do not store **TERBINAFINE GH** or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the medicine 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.

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 you have left over.

Product description

What TERBINAFINE GH tablets look like

TERBINAFINE GH 250 mg tablets are available in packs of 42 tablets.

TERBINAFINE GH 250 mg tablets are white to off-white, capsule-shaped, biconvex tablets debossed with 'T' and '250' on either side of the breakline on one side and a deep breakline on the other side.

Ingredients

Active ingredient:

TERBINAFINE GH contains 250 mg of terbinafine (as hydrochloride) as the active ingredient

Inactive ingredients:

- Microcrystalline cellulose
- Sodium starch glycollate type A
- Hypromellose
- Colloidal anhydrous silica
- Magnesium stearate
- Purified talc

Distributed in Australia by

Generic Health Pty Ltd
Level 1, 1102 Toorak Rd
Camberwell VIC 3124

Australian Registration Number

TERBINAFINE GH 250 mg tablets - AUST R 200224

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