

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I taking TINASIL?

TINASIL contains the active ingredient Terbinafine hydrochloride. TINASIL is used to treat fungal infections of fingernails and toenails, as well as ringworm (tinea) infections occurring in the groin and body, and tinea infections of the feet (athlete's foot).

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

### 2. What should I know before I take TINASIL?

Do not take if you have ever had an allergic reaction to TINASIL 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 take TINASIL?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TINASIL 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 take TINASIL?

- Your doctor will advise you on the appropriate dose.
- For skin infections: take 250 mg TINASIL once a day.
- For fungal infection of finger and toenails: take 250 mg TINASIL 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 take TINASIL?](#) in the full CMI.

### 5. What should I know while taking TINASIL?

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking TINASIL.</li><li>• Tell your doctor immediately if you develop any signs of an allergic reaction.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly.</li><li>• Do not use TINASIL in children.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• TINASIL may cause dizziness in some people. Avoid driving vehicles or using machines if you are dizzy.</li><li>• Be careful before you drive or use any machines or tools until you know how TINASIL affects you.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Store below 25°C.</li><li>• Keep your tablets in the original container until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while taking TINASIL?](#) 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.

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

### 1. Why am I taking TINASIL?

TINASIL contains the active ingredient Terbinafine hydrochloride. TINASIL belongs to a group of medications called antifungals.

**TINASIL tablets are used to treat:**

- fungal infections of fingernails and toenails (Onychomycosis)
- 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.

Terbinafine, the active ingredient in TINASIL tablets, works by killing the 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.

### 2. What should I know before I take TINASIL?

#### Warnings

##### Do not take TINASIL 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.
    - any other medicines, foods, preservatives or dyes. Your doctor will want to know if you are prone to allergies.
- 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.

- you have or ever had a problem with your kidneys or liver

TINASIL 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 and your liver is functioning normally now, your doctor may prescribe TINASIL tablets 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 they may ask you to stop taking TINASIL.

- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering

#### Check with your doctor if you:

- are pregnant or plan to become pregnant
- are breastfeeding
- if you have other medical conditions including if you have liver problems or any symptoms such as feeling sick, loss of appetite, weakness, vomiting, pain in the right upper park of tummy or yellowing of skin or eyes, dark urine or pale stools
- 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), serious skin reactions (such as Stevens-Johnson syndrome, a serious disorder of the skin with symptoms such as blisters, weakness, fever or toxic epidermal necrolysis)
- have or experience thickened patches of red/silver skin (psoriasis) or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus).
- have any blood disorders or experience weakness, unusual bleeding, bruising or frequent infections

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

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

TINASIL is not recommended during pregnancy. Your doctor will advise you regarding the possible risks and benefits of using TINASIL during pregnancy. There is no experience with use of TINASIL tablets 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. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use TINASIL during breastfeeding as terbinafine hydrochloride passes in breast milk. There is a possibility that your baby could be affected.

## Laboratory tests

Your doctor might do routine blood tests, liver function test before and during TINASIL.

## 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 TINASIL 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). You may have problems, such as bleeding between periods, while you are taking TINASIL tablets.
- some medicines used to treat an irregular heartbeat, heart problems, high blood pressure and migraines (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 1C, and monoamine oxidase inhibitors (MAOIs) Type B)
- cyclosporin, a medicine used to prevent organ transplant rejection or treat certain problems with the immune system
- drugs used for treatment of cough e.g. dextromethorphan
- some medicines for Parkinson's disease

**Medicines that may increase the effect of TINASIL include:**

- cimetidine or other similar medicines used to treat stomach ulcers
- other antifungal medicines such as Fluconazole, ketoconazole

**Medicines that may reduce the effect of TINASIL include:**

- 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 TINASIL.**

## 4. How do I take TINASIL?

### How much to take

- Follow your doctor's instructions on how many TINASIL tablets to take.
- The usual dose of TINASIL is one tablet (250 mg) each day. If you have kidney problems, the dose may be reduced to one-half a tablet each day.

### When to take TINASIL

- Take TINASIL 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 to take TINASIL

- Swallow the tablet with a full glass of water.
- If your doctor has advised that you take half a tablet, you may divide the tablet in half along the breakline.
- If you find that TINASIL upsets your stomach, try taking it immediately after a light meal.

### How long to take it

- 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. Your doctor will advise you regarding the duration of treatment.

- **Fungal skin infections (tinea):**

If you have a tinea infection of the feet (Athlete's foot), you will usually take TINASIL 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 TINASIL 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 your fungal infection does not improve. Your doctor will review and determine if an alternative antifungal therapy is needed.

### If you forget to take TINASIL

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

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

**Do not take a double dose to make up for the dose 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 when to take your medicine, ask your pharmacist for some hints.**

## If you take too much TINASIL

If you think that you or anyone else has taken too much TINASIL, urgent medical attention may be needed.

### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, 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.

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

## 5. What should I know while taking TINASIL?

### Things you should 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 the tablets.

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

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

- 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 notice any of the following:

- any signs of an allergic reaction
- 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
- become pregnant

Remind your doctor and pharmacist that you are about to be started on any new medicine.

Remind any doctor, dentist or pharmacist you visit that you are taking TINASIL.

### Things you should not do

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

- Do not take TINASIL tablets to treat any other complaints unless your doctor tells you to.

### Driving or using machines

**Be careful before you drive or operate any machines or tools until you know how TINASIL affects you.**

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

### Looking after your medicine

- Keep your tablets in the original container until it is time to take them.
- Store below 25°C.

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.

Heat and dampness can destroy some medicines.

### Keep it where young children cannot reach it.

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

### Getting rid of any unwanted medicine

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

Do not take 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
<b>General problems:</b> <ul style="list-style-type: none"><li>• low appetite</li><li>• joint pain</li><li>• muscle pain or weakness, not caused by exercise</li><li>• headache</li><li>• dizziness</li><li>• tiredness</li><li>• blurred vision</li><li>• vision problems</li><li>• fever, chills, body pain, dry cough</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>
<b>Skin problems:</b>	

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• hives</li> <li>• rash</li> <li>• itching</li> <li>• redness of the skin</li> </ul> <p><b>Tummy problems:</b></p> <ul style="list-style-type: none"> <li>• feeling sick</li> <li>• vomiting</li> <li>• uncomfortable feeling in tummy</li> <li>• excessive feeling of gas in the tummy</li> <li>• cramps or pain in tummy</li> <li>• diarrhoea</li> <li>• indigestion</li> <li>• excessive burping</li> <li>• swelling of your belly</li> </ul> <p><b>Other problems:</b></p> <ul style="list-style-type: none"> <li>• anxiety</li> <li>• depression.</li> </ul>	

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• unexplained weakness, tummy problems,</li> <li>• weakness, shortness of breath, dizziness or light-headedness, pale skin, headaches</li> <li>• fever and chills, mouth sores, sore throat</li> <li>• chest pain, weakness, fever, muscle stiffness</li> </ul> <p><b>Other problems:</b></p> <ul style="list-style-type: none"> <li>• hearing problems</li> <li>• partial loss of hearing</li> <li>• taste disturbance</li> <li>• loss of taste</li> <li>• decreased ability to smell or detect odours</li> <li>• loss of the sense of smell.</li> </ul>	

**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](http://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 TINASIL contains

Active ingredient (main ingredient)	Terbinafine (as the hydrochloride salt) 250 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• croscarmellose sodium</li> <li>• povidone</li> <li>• colloidal anhydrous silica</li> <li>• purified talc</li> <li>• magnesium stearate</li> </ul>

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

### What TINASIL looks like

TINASIL tablets are round, white to off-white tablets marked with "TF" over a breakline over "250" on one side and "G" on the other side (AUST R 104493).

## Serious side effects

Serious side effects	What to do
<p><b>General problems:</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• problems with your blood vessels having symptoms like fever, weight loss, tiredness, rash</li> </ul> <p><b>Tummy Problems:</b></p> <ul style="list-style-type: none"> <li>• pain in tummy, vomiting, blood in the stools (swelling of the stomach lining)</li> <li>• yellowing of the skin and eyes, feeling sick, light-coloured stools, dark colour urine</li> </ul> <p><b>Skin problems:</b></p> <ul style="list-style-type: none"> <li>• itchy rash, fever, joint pains</li> <li>• fever, red rash, painful red areas, blisters, peeling of layers of skin (may indicate serious skin reaction)</li> </ul> <p><b>Abnormal blood tests:</b></p> <ul style="list-style-type: none"> <li>• dark-coloured urine, weakness</li> <li>• weakness, feeling sick, swelling on arms, legs, or face</li> <li>• yellowing of skin or eyes, loss of appetite, vomiting</li> </ul>	<p><b>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.</b></p>

TINASIL tablets are supplied in blister packs containing 42 tablets.

### **Who distributes TINASIL**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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