

APO-TERBINAFINE

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 APO-TERBINAFINE?

APO-TERBINAFINE contains the active ingredient terbinafine hydrochloride and is used to treat fungal infections of the fingernails and toenails, tinea (ringworm) infections of the groin, body, tinea infections of the feet - referred to as "athlete's foot".

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

1. What should I know before I use APO-TERBINAFINE?

Do not use if you have ever had an allergic reaction to APO-TERBINAFINE 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 APO-TERBINAFINE?](#) in the full CMI.

2. What if I am taking other medicines?

Some medicines may interfere with APO-TERBINAFINE 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.

3. How do I use APO-TERBINAFINE?

- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.
- The usual dose of terbinafine is one tablet (250 mg) taken once each day.

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

4. What should I know while using APO-TERBINAFINE?

Things you should do	<ul style="list-style-type: none">• Make sure you are taking your tablet every day, continue taking it until your doctor tells you to stop.• This will ensure that all the infection is gone and will lessen the chance of the infection coming back once you stop taking this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not take this medicine 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery or doing jobs that require you to be alert while you are taking terbinafine until you know how it affects you.• This medicine may cause dizziness, light headedness, tiredness, and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light.• Heat and dampness can destroy some medicines.

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

5. 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. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine

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.

APO-TERBINAFAINE

Active ingredient(s): *Terbinafine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-TERBINAFAINE. **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 APO-TERBINAFAINE.**

Where to find information in this leaflet:

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

1. Why am I using APO-TERBINAFAINE?

APO-TERBINAFAINE contains the active ingredient terbinafine hydrochloride. APO-TERBINAFAINE is used to treat:

- fungal infections of the fingernails 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.

Terbinafine works by killing dermatophytes. However, drug resistance has been reported with the use of terbinafine in dermatophytes, especially *Trichophyton* species. Prescribers should take into consideration the local prevalence of drug resistance and if an alternate treatment should be considered.

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

Your doctor may have prescribed this medicine for another reason.

It is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

This medicine should not be used in children

2. What should I know before I use APO-TERBINAFAINE?

Warnings

Do not use APO-TERBINAFAINE if you have an allergy to:

- any medicine containing terbinafine
- any of the ingredients listed at the end of this leaflet

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 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 had a liver problem in the past and your liver is functioning normally now, your doctor may prescribe this medicine but may want to check your liver function before and during treatment.

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 this medicine.

Do not take this medicine:

- if you have or have had a problem with your kidneys
- if you take any medicines for any other condition
- if you are pregnant or whilst pregnant until you and your doctor have discussed the risks and benefits involved
- if you are breastfeeding. This medicine passes into breast milk. Do not take this medicine whilst breastfeeding as there is a possibility that your baby could be affected
- 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

Check with your doctor:

- if you have allergies to any other medicines, foods, preservatives or dyes.

- if you have or have had any of the following medical conditions:
 - problems with your liver
 - problems with your kidney
 - skin problems (e.g. psoriasis or lupus erythematosus)
 - blood disorders, or experience weakness, unusual bleeding, bruising or frequent infections
- if you are pregnant or plan to become pregnant or are breastfeeding.
- if you have skin problems such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of serious skin reactions), or rash due to high level of a specific type of white blood cells (eosinophilia).
- if you have or have had thickened patches of red/silver skin (psoriasis), or facial rash, joint pain, muscle disorder or fever (cutaneous and systemic lupus erythematosus).

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

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.

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

Do not take this medicine if you are pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

Do not breastfeed if you are taking this medicine.

This medicine passes into breast milk. Do not take this medicine whilst breastfeeding as there is a possibility that your baby could be affected.

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 interact with terbinafine. These include:

- some medicines used to treat depression and other mental disorders, including obsessive-compulsive disorders and panic attacks e.g. tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), and monoamine oxidase inhibitors (MAOIs).
- some medicines for Parkinson's disease

- some medicines used to treat an irregular heartbeat, heart problems, high blood pressure and migraines (e.g. metoprolol)
- some medicines used to treat stomach ulcers (e.g. cimetidine)
- certain antibiotics (e.g. rifampicin)
- dextromethorphan, a cough suppressant
- caffeine
- cyclosporin, used to help prevent organ transplant rejection, or to treat certain problems with the immune system
- fluconazole, to treat fungal infections
- oral contraceptives (birth control pills) – you may have problems, such as bleeding between periods, while you are taking terbinafine

warfarin, used to prevent blood clots.

These medicines may be affected by terbinafine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Other medicines not listed above may also interact with terbinafine. Your doctor can discuss with you the risks and benefits involved.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if this may affect APO-TERBINAFINE.

4. How do I use APO-TERBINAFINE?

How much to take

- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.
- The usual dose of terbinafine is one tablet (250 mg) taken once each day.
- Follow the instructions provided and use APO-TERBINAFINE until your doctor tells you to stop. [for antibiotics, replace with 'Follow the instructions provided when APO-TERBINAFINE was prescribed, including the number of days it should be taken.

How to take it

Swallow the tablet with a full glass of water.

If you find that terbinafine upsets your stomach, try taking it immediately after a light meal.

When to take APO-TERBINAFINE

- 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 APO-TERBINAFINE

- Continue taking your medicine for as long as your doctor tells you.
- Do not take it for longer than this.

If you forget to use APO-TERBINAFINE

If it is almost time for your next dose, 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 that you missed.

This may increase the chance of you experiencing side effects.

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 use too much APO-TERBINAFFINE

If you think that you have used too much APO-TERBINAFFINE, 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.

You may need urgent medical attention.

5. What should I know while using APO-TERBINAFFINE?

Things you should do

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

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

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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

Things you should not do

- Do not take this medicine 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-TERBINAFFINE affects you.

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

This medicine may cause dizziness, light headedness, tiredness, and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery 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 it does not return.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.
- If you take your medicine out of its original packaging, it may not keep well.
- Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light.
- Heat and dampness can destroy some medicines.

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 windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

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.

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine

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.

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
<ul style="list-style-type: none"> • nausea (feeling sick) or vomiting • upset stomach (heartburn, cramps, wind, belching) • loss of appetite • diarrhoea • aching joints or muscles • headache • dizziness or light headedness • tiredness, sleepiness • loss of or change in sense of taste, which usually returns to normal within several weeks of stopping terbinafine • other skin problems • psoriasis (thickened patches of red skin, often with silvery scales) • hair loss • tingling or numbness • decreased physical sensitivity • change in your vision or the appearance of your eye • 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) • decreased hearing, impaired hearing and/or perception of noises in the absence of sound (e.g. hissing or ringing) in ears 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none"> • chest pain • 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 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Very Serious side effects	What to do
<ul style="list-style-type: none"> • anemia • signs of a possible blood problem such as constant "flu-like" symptoms (fever, sore throat, mouth ulcers, chills, swollen glands, lack of energy) or unusual bleeding or bruising • any other signs of infection, apart from the fungal infection you are being treated for • 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 • symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>You may need urgent medical attention or hospitalisation.</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. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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 APO-TERBINAFFINE contains

Active ingredient (main ingredient)	Each tablet contains 250 mg of terbinafine (as hydrochloride) as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • methylcellulose • croscarmellose sodium • magnesium stearate • colloidal anhydrous silica

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

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

What APO-TERBINAFFINE looks like

APO-TERBINAFFINE is a 250mg Tablet: white, round, uncoated biconvex tablets with bevelled edges engraved with "APO" on one side and "TER" over "250" and scored through the centre of the other. **AUST R 100025**

Available in packs of 42 tablets

SPONSOR

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street Cremorne VIC 3121

Australia

Web: www.arrotex.com.au

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