

APO-Terbinafine

Contains the active ingredient terbinafine hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO-Terbinafine

It does not contain information about other forms of terbinafine that are available without a prescription from your pharmacy.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Terbinafine Tablet. It contains the active ingredient terbinafine.

It 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 this medicine for another reason.

It is available only with a doctor's prescription.

How it works

Terbinafine works by killing dermatophytes.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You have or have had a problem with your liver.
- You are hypersensitive to, or have had an allergic reaction to, terbinafine or any of

the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - problems with your liver
 - problems with your kidney
 - skin problems (e.g. psoriasis or lupus erythematosus)
 - blood disorders.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. This medicine passes into breast milk. Do not take this medicine whilst breastfeeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with terbinafine. These include:

- some medicines used to treat depression and other disorders, including obsessive-compulsive disorders and panic attacks
- 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, a medicine 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, a medicine used to prevent blood clots.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with terbinafine.

How to take this medicine

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information contained in this leaflet.

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The usual dose of terbinafine is one tablet (250 mg) taken once each day.

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 it

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 it for

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

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.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking terbinafine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- 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, ringing) in ears.

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

- 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
- 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.

The above are serious side effects that need medical attention. Serious side effects are rare. Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to terbinafine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

Storage and Disposal

Storage

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.

Do not store your medicine 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 this 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Terbinafine Tablet looks like

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.

APO-Terbinafine is available in packs of 42 tablets.

Ingredients

Each tablet contains 250 mg of terbinafine (as hydrochloride) as the active ingredient.

It also contains the following inactive ingredients:

- methylcellulose
- croscarmellose sodium
- magnesium stearate
- anhydrous silica.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Terbinafine 250mg Tablets (blister packs): AUST R 100025.

Sponsor

Apotex Pty Ltd
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