

# **APO-Terbinafine**

Terbinafine hydrochloride

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## **Consumer Medicine Information**

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

## **What is in this leaflet**

This leaflet answers some common questions about this medicine. 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 this medicine is used for**

Terbinafine 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.

Terbinafine works by killing 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.

There is no evidence that this medicine is addictive.

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 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.**

**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.

**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:**

- 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

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

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor 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).**

**Tell your doctor 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.**

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.

## **How to take this medicine**

**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 directions, ask your doctor or pharmacist for help.**

## **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.

## **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**

**Continue taking your medicine for as long as your doctor tells you.**

Do not take it for longer than this.

## **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 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 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 of this medicine. 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**

**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 of 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 be started 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 must 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.**

## **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.

## **Side effects**

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

All medicines have side effects. Sometimes they are serious but most of the time they are not.

**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 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 or 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

- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may occur in some patients.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

## **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. Protect from light.**

**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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **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. AUST R 100025.

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
- colloidal anhydrous silica

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

## **Sponsor**

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