

## PART III: CONSUMER INFORMATION

### APO-TERBINAFINE Terbinafine Hydrochloride Tablets

This leaflet is part III of a three-part “Product Monograph” published when APO-TERBINAFINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-TERBINAFINE. Contact your doctor or pharmacist if you have any questions about the drug.

Keep this leaflet. You may need to read it again. This medicine has been prescribed only for you. Do not give it to anybody else or use it for other illnesses. Read all of this leaflet carefully before you start treatment. Follow all your doctor’s instructions carefully, even if they differ from the general information contained in this leaflet.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

APO-TERBINAFINE is used to treat fungal infections of skin, fingernails and toenails:

- APO-TERBINAFINE tablets are used to treat fungal infections of the nail (toes, fingers) and may be used for certain fungal skin infections that do not respond to topical treatment.

Consult your doctor to confirm which type of fungal skin infection you have. Your doctor can determine if APO-TERBINAFINE is the right treatment for you.

The treatment should only be taken as prescribed by your doctor. Some evidence of infection may still be present at the end of treatment. This will gradually diminish.

##### What it does:

Terbinafine interferes in the production of a substance (ergosterol) that the fungus needs to grow and causes a build-up of another substance in the cells (squalene). Both actions cause the death of the fungus and elimination of the infection.

##### When it should not be used:

Do not use APO-TERBINAFINE if you are allergic to terbinafine (the active antifungal ingredient) or any of the ingredients in the formulation (*See What the nonmedicinal ingredients are*). If you think you may be allergic, ask your doctor for advice.

Do not use APO-TERBINAFINE if you have chronic or active liver disease.

##### What the medicinal ingredient is:

terbinafine hydrochloride

##### What the nonmedicinal ingredients are:

colloidal silicon dioxide, croscarmellose sodium, magnesium stearate and methylcellulose.

##### What dosage forms it comes in:

250 mg tablets

## WARNINGS AND PRECAUTIONS

### Serious Warnings and Precautions

Terbinafine hydrochloride tablets must not be used if you have pre-existing chronic or active liver disease. Serious and life-threatening cases of liver failure, including death, or requiring liver transplant, have been reported in patients with or without pre-existing chronic or active liver disease receiving APO-TERBINAFINE Tablets.

Stop taking APO-TERBINAFINE tablets and consult your doctor immediately should you develop jaundice (yellowness of skin and/or eyes or other symptoms). See *Table of Serious Side Effects*.

Your doctor may order blood tests before you start APO-TERBINAFINE and during APO-TERBINAFINE treatment.

##### **Before you use APO-TERBINAFINE, talk to your doctor if you:**

- have or have a history of any other medical problems such as liver or kidney problems, blood diseases (e.g. anemia), serious skin reactions, or alcohol abuse
- if you have or have had liver problems, your doctor may require blood tests before and

during APO-TERBINAFFINE treatment to test liver function

- are allergic to any other medicines (either prescription or non-prescription) or foods
- are pregnant or intend to become pregnant while using APO-TERBINAFFINE
- are breast-feeding; terbinafine is excreted in breast milk.

**Contact your doctor immediately, while taking APO-TERBINAFFINE, if you develop conditions such as:**

- liver problems with symptoms such as persistent nausea, vomiting, abdominal pain, dark urine, pale stools, fatigue, loss of appetite, yellowing of the skin and eyes
- serious skin reactions such as blistering or peeling skin, blistering of the lips, eye or mouth, red/inflamed skin, hives, fever (due to skin reactions), rash (due to high white blood cell count-eosinophilia)
- experience symptoms of lupus erythematosus such as thickened patches of red/silver skin (psoriasis), joint pain, muscle disorder/pain and fever

blood disorder with symptoms such as weakness, unusual bleeding, bruising, sore throat or frequent infections

### **INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including herbal medicines, oral contraceptives (birth control pills) and nonprescription medicines. Some other medicines may interact with APO-TERBINAFFINE. These include:

- some medicines used to treat infectious diseases called antibiotics (e.g. rifampicin),
- some medicines used to treat mood disorders (some antidepressants (such as tricyclic antidepressants, selective serotonin reuptake inhibitors including class 1A, 1B and 1C, monoamine oxidase inhibitors Type B, desipramine),
- some medicines used to treat irregular heart rhythm (antiarrhythmics (e.g. propafenone, amiodarone),
- some medicines used to treat high blood pressure (e.g. beta-blockers such as metoprolol),
- theophylline, a medicine used to relieve bronchospasm in asthma
- some medicines used to treat cough (e.g. dextromethorphan),
- cyclosporine, a medicine used to

control your body's immune system (e.g. in order to prevent rejection of transplanted organs).

- St John's wort [*Hypericum perforatum*], a herbal medicine used to treat depression

Some cases of menstrual irregularities and pregnancies have been reported in patients taking terbinafine concomitantly with oral contraceptives; however, the rate of occurrence appears to be within the background incidence for patients taking oral contraceptives alone.

### **PROPER USE OF THIS MEDICATION**

To help clear up your infection completely, it is very important that you keep taking this medicine for the prescribed treatment period, even if your symptoms begin to clear up or you begin to feel better after a few days. Since fungal infections may be very slow to clear up, stopping your medication too soon can cause the symptoms and the fungal infection to flare up again.

#### **Missed Dose:**

Try not to miss any doses. If you do miss a dose, take it as soon as possible. However, if it is almost time for your next dose (up to 4 hours), skip the missed dose and go back to your regular schedule. Do not double the doses and never make dose changes on your own. Take as prescribed by your doctor.

#### **Usual Adult Dose**

Follow your doctor's instructions carefully. Do not exceed the recommended dosage. If you have the impression that the effect of APO-TERBINAFFINE is too strong or too weak, talk to your doctor or pharmacist.

Adults: 125 mg twice daily or 250 mg once daily.

Taking APO-TERBINAFFINE at the same time each day will help you remember when to take your medicine. APO-TERBINAFFINE tablets can be taken on an empty stomach or after a meal.

You can take APO-TERBINAFFINE tablets if you are aged 65 years and over at the same dose as younger adults.

The duration of treatment varies according to the indication and the severity of infection:

**TABLE 1**

Indication	Duration of Treatment
Onychomycosis (of fingers and toes)	6 weeks to 3 months
Skin Infections Tinea pedis (interdigital & plantar/moccasin type)	2-6 weeks
Tinea corporis, cruris	2-4 weeks

**Overdose:**

Symptoms caused by an overdose of APO-TERBINAFINE tablets include headache, nausea, stomach pain and dizziness.

If you think you have taken too much APO-TERBINAFINE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

As with all medicines, some patients taking APO-TERBINAFINE tablets may experience some unwanted effects (side effects), although not everybody gets them.

**The following side effects have been reported with terbinafine hydrochloride tablets:**

Very common (*likely to affect more than 1 in every 10 patients*): headache, nausea, mild abdominal pain, stomach discomfort after meal (heartburn), diarrhea, swelling or bloating (a feeling of fullness) of the abdomen, loss of appetite, skin rashes (itchy), joint pain and muscle pain.

Common (*likely to affect 1 to 10 in every 100 patients*): Mood disorder (depression), disturbance or loss of sense of taste, dizziness, eye disorder and tiredness. If you suffer dizziness, do not drive or operate machinery.

Uncommon (*likely to affect 1 to 10 in every 1,000 patients*): If you notice abnormal pale skin, mucosal lining or nail beds, unusual tiredness or weakness or breathlessness on exertion (possible signs of a disease that affects the level of red blood cells), anxiety, tingling or numbness and decreased skin sensitivity, increased sensitivity of the skin to sun, noises (e.g. hissing) in ears, fever and weight loss.

Rare (*likely to affect less than 1 to 10 in every 10,000 patients*): Yellow eyes or skin (liver

problems) and abnormal liver function test results.

Very rare (*likely to affect less than 1 in every 10,000 patients*): Decrease in certain types of blood cells, lupus (an autoimmune disease), serious skin reactions, allergic reactions, psoriasis-like skin eruptions (rash with silver coloured appearance), worsening of psoriasis, skin rash with flaking or peeling and hair loss.

If you experience smell, taste, visual or hearing disorders or symptoms of depression, then stop using APO-TERBINAFINE and call your doctor.

If any of the listed side effects affect you severely, discuss this with your doctor.

Other side effects not listed above may also occur in some patients. If you notice any other side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Some side effects could be serious:

- if you develop fever, shivering, a sore throat or mouth ulcers due to infections and weakness or if you get infections more frequently or
- if you experience difficulty in breathing, dizziness, swelling mainly of the face and throat, flushing, crampy abdominal pain and loss of consciousness or if you experience symptoms such as joint pain, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions).
- If you develop any skin problems such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever.
- If you develop any skin problems.
- If you experience severe upper stomach pain with radiation to the back (possible signs of pancreas inflammation).
- If you experience unexplained muscle weakness and pain or dark (red-brown) urine (possible signs of muscle necrosis).

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
<b>Rare</b>	Liver problems, sometimes fatal with symptoms such as persistent nausea and vomiting, abdominal pain, fatigue, loss of appetite, dark urine, pale stools or jaundice (yellowing of the skin and eyes).			√
<b>Very rare</b>	Blood abnormalities with symptoms of sore throat, fever, mouth sore, unusual bleeding or bruising.			√
	Inflammation of the blood vessels (vasculitis) or the pancreas (pancreatitis)			√
	Serious allergic reactions (anaphylactic or serum sickness reactions) or infections			√
	Muscle breakdown (rhabdomyolysis)			√
	Immune system disorders (lupus)			√
	Serious skin reactions (blistering, peeling skin)			√

***This is not a complete list of side effects. For any unexpected effects while taking APO-TERBINAFINE, contact your doctor or pharmacist.***

## HOW TO STORE IT

Store at temperatures between 15° and 30°C. Protect from light.

Keep out of reach and sight of children.

## Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

### 3 ways to report:

- Online at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:

- Fax to 1-866-678-6789 (toll-free), or
- Mail to: Canada Vigilance Program  
Health Canada, Postal Locator  
0701E  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

***NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.***

## MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at:  
<http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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