PART III: CONSUMER INFORMATION

Pr TERBINAFINE
Terbinafine Hydrochloride Tablets

This leaflet is part III of a three-part "Product Monograph" published when 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 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:
TERBINAFINE is used to treat fungal infections of skin, fingernails and toenails.

Consult your doctor to confirm which type of fungal skin infection you have. Your doctor can determine if 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 TERBINAFINE (terbinafine hydrochloride) 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 TERBINAFINE if you have chronic or active liver disease.

What the medicinal ingredient is:
Terbinafine Hydrochloride

What the non-medicinal ingredients are:
- colloidal anhydrous silica
- hydroxy propylmethyl cellulose
- magnesium stearate
- microcrystalline cellulose
- sodium starch glycolate

What dosage forms it comes in:
250 mg Tablet

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
TERBINAFINE 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-exising chronic or active liver disease receiving terbinafine hydrochloride tablets.

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

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

Before you use TERBINAFINE, talk to your doctor if you:

- have a history of any other medical problems such as liver or kidney problems, blood diseases (e.g. anemia), serious skin reaction, or alcohol abuse;
- If you have or have had liver problems, your doctor may require blood tests before and during TERBINAFINE treatment to test liver function;
- are allergic to any medicines (either prescription or nonprescription), or foods;
- are pregnant or intend to become pregnant while using TERBINAFINE;
- are breast-feeding; terbinafine hydrochloride is excreted in breast milk.

Contact your doctor immediately, while taking TERBINAFINE, 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 non-prescription medicines. Some other medicines may interact with TERBINAFINE. 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 serotonine 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 hydrochloride 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 TERBINAFINE is too strong or too weak, talk to your doctor or pharmacist.

Adults: 250 mg once per day.

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

You can take TERBINAFINE 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

If there are no signs of improvement after two weeks you should talk to your doctor.

Relief of clinical symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after one week, contact your doctor.

There are other measures that you can take to help clear up your infection and make sure it does not return. For example, keep the infected areas dry and cool and change clothing that is in direct contact with the infected area(s) daily.

Overdose:

Symptoms caused by an overdose of terbinafine hydrochloride tablets include headache, nausea, stomach pain and dizziness.

In case of drug overdose, contact a health care practitioner, 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 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 tablets:

Very common (*likely to affect more that 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 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 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	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).			√
Very rare	Blood abnormalities with symptoms of sore throat, fever, mouth sore, unusual bleeding or bruising, low level of red blood cells (anemia)			√
	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)			√

HOW TO STORE IT

- Store at temperatures between 15°C and 30°C.
- Protect tablets from light.
- Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sanis Health Inc., at:
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or quality@sanis.com

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