

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTERBINAFINE - 250

Terbinafine Tablets

Read this carefully before you start taking **TERBINAFINE - 250** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TERBINAFINE - 250**.

Serious Warnings and Precautions

Do not take TERBINAFINE - 250 tablets 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 taking TERBINAFINE - 250 tablets.

Stop taking TERBINAFINE - 250 tablets and consult your doctor immediately if you develop jaundice (yellowness of skin and/or eyes). See Table of [Serious side effects and what to do about them](#).

Your doctor may order blood tests before you start TERBINAFINE - 250 and during TERBINAFINE - 250 treatment.

What is TERBINAFINE - 250 used for:

TERBINAFINE - 250 is used to treat fungal infections of skin, fingernails and toenails:

- TERBINAFINE - 250 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.

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.

How does TERBINAFINE - 250 work?

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.

What are the ingredients in TERBINAFINE - 250?

Medicinal ingredient: Terbinafine hydrochloride

Non-medicinal ingredients: Colloidal silicon dioxide, croscarmellose sodium, magnesium stearate and methylcellulose.

TERBINAFINE - 250 comes in the following dosage forms:

Tablets: 250 mg

Do not use TERBINAFINE - 250 if:

- you are allergic to terbinafine (the active antifungal ingredient) or any of the ingredients in the formulation (See [What are the ingredients in TERBINAFINE - 250](#)). If you think you may be allergic, ask your doctor for advice.
- you have chronic or active liver disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TERBINAFINE - 250. Talk about any health conditions or problems you may have, including if you:

- have or have had a history of liver or kidney problems, blood diseases (e.g. anemia), serious skin reactions, or alcohol abuse
- you have or have had liver problems, your doctor may require blood tests before and during TERBINAFINE - 250 treatment to test liver function
- are pregnant or plan to become pregnant while using TERBINAFINE - 250.
- are breast-feeding or plan to breast-feed; oral TERBINAFINE - 250 is excreted in breast milk.

Other warnings you should know about:

Contact your doctor immediately, while taking TERBINAFINE - 250, 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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

- Tell your doctor or pharmacist if you are taking or have recently taken oral contraceptives or birth control pills.

The following medicines may interact with TERBINAFINE - 250:

- 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.

How to take TERBINAFINE - 250:

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.

Usual dose:

Follow your doctor's instructions carefully. Do not exceed the recommended dosage. If you feel that the effect of TERBINAFINE - 250 is too strong or too weak, talk to your healthcare professional.

Adults: 250 mg once daily.

- Taking TERBINAFINE - 250 at the same time each day will help you remember when to take your medicine.
- TERBINAFINE - 250 tablets can be taken on an empty stomach or after a meal.
- You can take TERBINAFINE - 250 tablets if you are aged 65 years and over at the same dose as younger adults.

Overdose:

Symptoms caused by an overdose of TERBINAFINE - 250 tablets include headache, nausea, stomach pain and dizziness.

If you think you, or a person you are caring for, have taken too much TERBINAFINE - 250, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

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.

What are possible side effects from using TERBINAFINE - 250?**The following side effects have been reported with terbinafine 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*): 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, psoriasis-like skin eruptions (rash with silver coloured appearance), worsening of psoriasis, skin rash with flaking or peeling and hair loss.

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	
RARE			
Liver problems: sometimes fatal 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: sore throat, shivering, fever, mouth sore, weakness, unusual bleeding or bruising or getting infections frequently			✓
Serious allergic reactions (anaphylactic or serum sickness reactions) or infections: 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			✓
Skin reactions: rash, red skin, blistering of lips, eyes or mouth, peeling skin			✓
UNKNOWN/ NOT KNOWN			
Inflammation of the blood vessels (vasculitis): rash, fever, or appearance of purplish-red spots under the skin surface			✓
Inflammation of pancreas (pancreatitis): severe upper stomach pain with radiation to the back			✓
Muscle breakdown			✓

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	
(rhabdomyolysis): severe muscle cramps, aches and pain, or dark (red-brown) urine, feeling unusually tired			
Immune system disorders (lupus): facial rash, swollen joints or joint pain, muscle disorder, tiredness, fever			✓
Smell, taste, visual or hearing disorders or symptoms of depression			✓

These are not all the possible side effects you may have when taking TERBINAFINE - 250. If you experience any side effects not listed here, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

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

If you want more information about TERBINAFINE - 250:

- Talk to your healthcare professional
- • Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca.

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