Package leaflet:
Information for the user

Terbinafine 250 mg tablets

(terbinafine)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Terbinafine is and what it is used for

Terbinafine belongs to a group of medicines called antifungals. It is used for the treatment of fungal infections of the skin (including those in between the fingers and toes) and of the nails.

2. What you need to know before you take Terbinafine

Do not take Terbinafine
- if you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe kidney problem.
- if you have a severe liver problem
- if you are breast-feeding

Warnings and precautions
Talk to your doctor or pharmacist before taking Terbinafine.
- if you have liver problems or a disease which may affect your liver.
- if you have psoriasis (skin disease with raised red patches of skin covered with silvery scales).
- if you have kidney problems.
- develop severe reduction in the number of white blood cells which make infections more likely (agranulocytosis) or serious illness with blistering of the skin (toxic epidermal necrolysis). You should stop taking Terbinafine and see your doctor immediately if you experience these side effects which are known to occur very rarely (see section 4).
- if you have (cutaneous and systemic lupus erythematosus)

If any of the above warnings applies to you or has applied to you in the past, consult your doctor.

Children should not normally be given Terbinafine tablets.

Other medicines and Terbinafine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- the antibiotic, rifampicin (decreases the level of terbinafine in your blood).
- cimetidine (a medicine for stomach ulcers and heartburn) increases the level of terbinafine in your blood.
- Antidepressants including tricyclic antidepressants, SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)
- Beta-blockers or anti-arrhythmics for heart problems
- oral contraceptives (the pill). Irregular periods and abnormal menstrual bleeding which may be between periods may occur in female patients.
- Medicines to treat heart problems (eg propafenone, amiodarone)
- ciclosporin (medicine used to prevent rejection of organs or tissues following a transplant or to treat certain skin conditions like psoriasis and eczema or to treat rheumatoid arthritis)
- tolbutamide for diabetes
- triazolam for relieving anxiety and/or trouble sleeping
- terfenadine for hay fever or other allergies
- Medicines used to treat fungal infections (eg fluconazole, ketoconazole)
- Medicines used to treat cough (eg dextromethorphan)
- Caffeine

Please note that the above medicines may be known to you by other names. Always thoroughly check the information leaflet of the medicines you are already using and check with your doctor or pharmacist before taking Terbinafine if you are taking any of the above sorts of medicines.

You should have blood tests before and during treatment with Terbinafine tablets to monitor your liver function.

Terbinafine with food and drink
Taking food and drink has no influence on terbinafine treatment.

Pregnancy and breast-feeding
If you are pregnant, think you are pregnant or breast – feeding; you should not take Terbinafine unless your doctor tells you to. If you become pregnant whilst taking this medicine, you should tell your doctor as soon as possible.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Some people have reported feeling dizzy or giddy while they are taking Terbinafine. If you feel like this you should not drive or operate machinery.

Terbinafine contains Sodium
Terbinafine tablets contains Sodium. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Terbinafine

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

Adults:
The dose you are prescribed will depend on the type of infection and how bad it is.
The recommended dose is 250 mg Terbinafine daily. You should swallow your tablet with a glass of water. The tablets can be taken with or without food.
If you suffer from kidney problems, your doctor may prescribe half the recommended dose.

Duration of treatment:
Your doctor will tell you how long your treatment with terbinafine will last.
- For general fungal skin infections, your treatment will probably last for 4 weeks.
- Treatment for skin infections affecting the groin or body will normally last between 2 to 4 weeks and those involving feet may last between 2 to 6 weeks.
- For nail infections your treatment may last between 6 weeks and 3 months, although treatment for toenail infections may continue for 6 months or longer.

Complete resolution of the signs and symptoms of the infection may not occur until several weeks after treatment has stopped and the infection has been cured.

Children and adolescents (below 18 years of age)
Terbinafine is not recommended for children and adolescents under 18 years.

If you take more Terbinafine than you should
If you or someone you know has taken more tablets than they should, consult your doctor or the nearest hospital casualty department immediately. Take this leaflet or some tablets with you so your doctor will know what you have taken.You may feel dizzy, sick and have a headache and/or stomach pain.

If you forget to take Terbinafine
If you forget to take Terbinafine at the right time, take them as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Terbinafine
Do not stop taking terbinafine without consultation with your doctor, even if the infection heals.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

N05984

Black

Version: 10
Date & Time: 09.05.2025 & 5:15 PM
Submission Code: N05984-U3

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets effects. Any side effects are usually mild or moderate and don't last for too long.

Some side effects can be serious
Stop taking the tablets and tell your doctor immediately if you notice any of the following rare symptoms:

- Difficulty in breathing, dizziness, swelling mainly of the face and throat, flushing, crampy abdominal pain, stiffness, rash, fever or swollen / enlarged lymph nodes (possible signs of severe allergic reactions)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish spots under the skin surface (signs of blood vessel inflammation)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation)
- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible signs of muscle breakdown)
- Severe skin reactions including rash, light sensitivity, blistering and wheals
- Weakness, unusual bleeding, bruising, abnormal pale skin, unusual tiredness, or weakness or
- breathlessness on exertion or frequent infections (these may be signs of a blood disorder)
- Yellowing of your skin or eyes, unusually dark urine or pale stools, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (this may indicate serious liver problems), increase in liver enzymes which may be noted on a blood test result.

Very common (may affect more than 1 in 10 people)

- loss of appetite,
- stomach ache, feeling of fullness, diarrhoea, indigestion (dyspepsia), feeling sick (nausea),
- Joint pain (arthralgia) and muscle pain (myalgia).
- Rash, reddening of skin with itching and hives (urticaria).

Common (may affect up to 1 in 10 people):

- Headache

Uncommon (may affect up to 1 in 100 people):

- Taste loss and taste disturbance. This usually disappears within several weeks after you stop taking the medicine. However, a very small number of people, (less than 1 in 10,000), have reported that the taste disturbance lasts for some time and, as a result, they go off their food and lose weight. There have also been reports of some people experiencing anxiety or symptoms of depression as a result of these taste disturbances.

Rare (may affect up to 1 in 1,000 people):

- increased hepatic enzyme levels or liver failure.
- abnormal liver function, including liver inflammation (hepatitis) and jaundice (yellowing of the skin and eyes), biliary obstruction (cholestasis), abnormal liver function test results, liver function disorders (primarily cholestatic in nature.
- Feeling unwell (malaise), dizzy
- Numbness or tingling of the arms or legs

Very rare (may affect up to 1 in 10,000 people):

- Reductions in the number of different types of blood cells which may increase the risk of severe infection, bleeding or may cause shortness of breath and tiredness (agranulocytosis, neutropenia, thrombocytopenia).
- condition which may cause a very wide variety of symptoms such as joint pain, kidney problems, rash and fever (systemic lupus erythematosus).
- Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals),
- Hair loss.
- Toxic epidermal necrolysis (a serious illness with blistering and loss of the skin),
- Serious allergic reactions, which causes swelling of the face or throat (angio odema)
- Vertigo (dizziness)
- increased sensitivity of your skin to sunlight

Not known (frequency cannot be estimated from the available data):

- allergic reactions (including anaphylaxis),
- loss of smell (anosmia) which may be permanent,
- blurred vision, decreased sharpness of vision,
- loss of hearing (hypoacusis,),
- swelling of the blood vessels (vasculitis),
- swelling of the pancreas (pancreatitis),
- break-down of damaged muscle (rhabdomyolysis),
- flu-like illness or fever, fatigue
- rash associated with an increase in certain cells in the blood (eosinophilia).
- psoriasiform eruptions or exacerbation of psoriasis.
- rash with the formation of flakes or peeling of the skin, hair loss. Severe skin reactions with blistering or peeling of the skin (e.g. erythema exudativum multiforme [EEM], acute generalized exanthematic pustulosis [AGEP]).
- increase in blood of a muscle enzyme called creatine phosphokinase (may be found on a blood test),
- anxiety and depressive symptoms
- pancytopenia

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Terbinafine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton . The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Terbinafine contains

- The active substance is terbinafine. Each tablet contains 250 mg of terbinafine (as terbinafine hydrochloride).
- The other ingredients are cellulose microcrystalline, sodium starch glycolate (type A), silica colloidal anhydrous, hypromellose and magnesium stearate.

What Terbinafine looks like and contents of the pack
Tablets

White to off-white, round uncoated, biconvex bevelled edge tablets with breakline and 'D' debossed on one side and '74' on the other side. The tablet can be divided into equal halves.

Terbinafine tablets are available in PVC/PVDC/Aluminum blister packs of 6, 7, 8, 10, 12, 14, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98, 100, 250 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder
Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF 26, Hal Far Industrial Estate, Hal Far
Brizebbugia BBG 3000
Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This leaflet was last revised in 05/2025.

N05984