

PACKAGE LEAFLET: INFORMATION FOR THE USER
TERBINAFINE 250mg TABLETS

P2987T

(terbinafine hydrochloride)

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 only. 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 tablets are and what they are used for
2. What you need to know before you take Terbinafine tablets
3. How to take Terbinafine tablets
4. Possible side effect
5. How to store Terbinafine tablets
6. Contents of the pack and other information

1. What Terbinafine tablets are and what they are used for

Terbinafine hydrochloride, the active ingredient in these tablets, belongs to a group of medicines called antifungals.

Terbinafine tablets is used to treat fungal infections of the skin and nails.

2. What you need to know before you take Terbinafine tablets

Do not take Terbinafine tablets if you:

- are **allergic to Terbinafine or any of the other ingredients** of Terbinafine tablets (see list of ingredients in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- are breast-feeding
- have or have had any **liver problem**

Warnings and precautions

Talk to your doctor or pharmacist before taking Terbinafine tablets.

Take special care with Terbinafine tablets (and speak to your doctor) if you:

- have liver problems or a hepatic disease which may affect your liver
- have liver dysfunction or very rare cases of serious liver failure which may affect your liver
- have pre-existing psoriasis (skin disease with raised red patches of skin covered with silvery scales)
- have serious skin reactions (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms)
- 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)
- have blood dyscrasias (neutropenia, thrombocytopenia, pancytopenia)
- have renal impairment (creatinine clearance less than 50 ml/min or serum creatinine more than 300 micro mol/L)
- have systemic lupus erythematosus (SLE)
- have rash due to a high level of a specific type of white blood cells
- have pregnant or trying to become pregnant

Children

Children should not normally be given Terbinafine tablets.

Other medicines and Terbinafine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking:

- the antibiotic rifampicin for tuberculosis (decreases the level of terbinafine in your blood)
- cimetidine for gastric problems such as indigestion or stomach ulcers (increases the level of terbinafine in your blood)
- medicines used to treat depression including tricyclic and SSRIs
- antidepressants like clomipramine, nortriptyline, desipramine, fluoxetine, and paroxetine
- medicines used to treat high blood pressure or heart problems such as beta blockers e.g. atenolol
- medicines used to treat a fast or irregular heart beat such as antiarrhythmics e.g. flecainide, propafenone
- oral contraceptives (the pill) as irregular periods or breakthrough bleeding may occur in female patients
- 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)
- medicines used to treat fungal infections (eg fluconazole, ketoconazole)
- medicines used to treat cough (eg dextromethorphan)
- caffeine

It may still be all right for you to be given Terbinafine tablets and your doctor will be able to decide what is suitable for you.

Terbinafine tablets with food and drink

Food/meals have no influence on the effectiveness of Terbinafine. Terbinafine may be taken with or without food.

Pregnancy and breast-feeding

You should not take Terbinafine tablets if you are pregnant unless your doctor tells you to. If you become pregnant whilst taking this medicine, you should tell your doctor as soon as possible.

You should not take Terbinafine tablets if you are breast-feeding. 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 tablets. If you feel like this, you should not drive or operate machinery.

Important information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Additional monitoring tests

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

3. How to take Terbinafine tablets

The doctor will decide what dose of Terbinafine Tablets you should take.

Always take Terbinafine tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults, including elderly, is 250 mg (one tablet) once daily:

- For skin infections, continue taking the tablets for **2 to 6 weeks**.
- For nail infections, treatment usually last for between **6 weeks and 3 months**, although some patients with toenail infections may need to be treated for **6 months or longer**.
- Swallow the tablets whole with a glass of water.

Patients with a liver or kidney disorder:

A reduced dose may be required. If your kidneys are not working very well, your doctor may reduce the dose of Terbinafine tablets you take.

Method of Administration

The tablet should be swallowed whole with water. They may be taken with or without food.

If you take more Terbinafine tablets than you should

Contact your doctor, pharmacist or nearest hospital immediately. The symptoms of overdose are headache, feeling sick (nausea), upper abdominal pain and dizziness.

If you forget to take Terbinafine tablets

If you miss a dose, take it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Terbinafine tablets

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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects are important and will require immediate action if you experience them.

Some side effects can be serious.

You should stop taking Terbinafine and see your doctor immediately if the following symptoms occur:

- Yellowing of your skin or eyes. Unusually dark urine or pale faeces, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (this may indicate liver disorder such as liver failure, jaundice, cholestasis or hepatitis), increase in liver enzymes which may be noted on a blood test result (rare)
- Severe skin reactions including rash, light sensitivity, blistering or wheals:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin in more than 30% of the body surface (toxic epidermal necrolysis) (very rare)
 - skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme) (very rare)
 - redness and shedding of skin over a larger area of the body, which may be itchy or painful (dermatitis exfoliative, dermatitis bullous) (very rare)
 - usually drug-related skin reaction with rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (acute generalized exanthematous pustulosis, AGEP) (not known)
- Difficulty breathing, dizziness, swelling mainly of the face and throat, flushing, crampy abdominal pain, stiffness, rash, fever, swollen/enlarged lymph nodes or joint pain (possible signs of severe allergic reactions, cutaneous or systemic lupus erythematosus (SLE)) (very rare)
- Weakness, unusual bleeding, bruising, abnormal pale skin, unusual tiredness, or weakness or breathlessness on exertion or frequent infections (this may be a sign of blood disorders such as agranulocytosis, neutropenia or thrombocytopenia) (very rare)
- Severe reduction in the number of all types of blood cells, including red and white blood cells as well as platelets (anaemia pancytopenia) (not known)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish spots under the skin surface (signs of blood vessel inflammation) (vasculitis) (not known)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation) (pancreatitis) (not known)
- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible signs of muscle breakdown) (rhabdomyolysis) (not known)

The side effects listed below have also been reported.

Very common – may affect more than 1 in 10 people:

- Loss of appetite
- Stomach problems such as pain, indigestion, feeling full or bloated
- Diarrhoea
- Nausea
- Itching, rash or swelling (rash, urticaria)
- Pains in the muscles and joints (myalgia and arthralgia)

Common – may affect up to 1 in 10 people:

- Headache

Uncommon – may affect up to 1 in 100 people:

- Anxiety or symptoms of depression as a result of taste disturbances (hypogeusia)
- Dysgeusia including ageusia, dizziness Loss of weight associated to taste disorders

Rare – may affect up to 1 in 1,000 people:

- General feeling of being unwell (malaise)
- Numbness or tingling (paraesthesia, hypoaesthesia)
- Cases of serious hepatic dysfunction, including hepatic failure, hepatic enzymes increased, jaundice, cholestasis and hepatitis.

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

- A feeling of dizziness or "spinning" (vertigo)
- Hair loss (alopecia)
- Menstrual disturbance, bleeding or spotting experienced between menstrual periods or during pregnancy
- Agranulocytosis, neutropenia, thrombocytopenia
- Anaphylactoid reactions (including angioedema), cutaneous or systemic lupus erythematosus
- Ear and labyrinth disorders (vertigo)
- Photosensitivity reactions (alopecia)
- Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, toxic skin eruption, dermatitis exfoliative, dermatitis bullous.

Not known – frequency cannot be estimated from the available data:

- Partial or complete loss of the sense of smell (anosmia, hyposmia)
- Visual impairment, vision blurred, reduced visual acuity
- Partial or total inability to hear (hypoacusis) and tinnitus
- Inflammation of the blood vessels (vasculitis)
- Inflammation of the pancreas (pancreatitis)
- Psoriasisiform eruptions, or exacerbation psoriasis. Serious skin reactions (e.g. acute generalized exanthematous pustulosis (AGEP)).
- Acute inflammatory condition with the development of erythematous skin lesions and joint swelling with or without fever (serum sickness-like reaction, SSLR)
- Increase of creatine phosphokinase in the blood
- The breakdown of muscle tissue (rhabdomyolysis) Drug reaction with eosinophilia and systemic symptoms (DRESS)
- Influenza-like illness, fatigue, pyrexia

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 tablets

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

This medicinal product does not require special temperature storage conditions. Keep blister in the outer carton.

Do not take this medicine after the expiry date, which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.

If you notice any visible signs of deterioration in the tablets, such as chipped, broken or discoloured tablets, take them to your pharmacist for advice before taking them.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the Pack and other information

What Terbinafine tablets contain:

- The active substance is terbinafine hydrochloride.
Each tablet contains 250 mg of terbinafine (as 281.29mg terbinafine hydrochloride).
- The other ingredients are: cellulose microcrystalline (E460), sodium starch glycolate, hypromellose (E464), silica colloidal anhydrous, magnesium stearate (E572), ferric oxide E172 (Iron oxide red).

What Terbinafine tablets look like and contents of the pack

Terbinafine tablets are light pink with a mottled surface that is round and biconvex with "250" written on one side and break line on the other side. Blister packs of 14 or 28 or 42 or 56 tablets in cartons. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

This leaflet was last revised in 08/2024.

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- are breast-feeding
- have or have had any **liver problems**

Warnings and precautions

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- have liver problems or a hepatic disease which may affect your liver
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Terbinafine tablets with food and drink

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Pregnancy and breast-feeding

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Patients with a liver or kidney disorder:

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Method of Administration

The tablet should be swallowed whole with water. They may be taken with or without food.

If you take more Terbinafine tablets than you should

Contact your doctor, pharmacist or nearest hospital immediately. The symptoms of overdose are headache, feeling sick (nausea), upper abdominal pain and dizziness.

If you forget to take Terbinafine tablets

If you miss a dose, take it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Terbinafine tablets

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 product, ask your doctor or pharmacist.

400 mm

150 mm

Size: 150 x 400 mm

Front

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects are important and will require immediate action if you experience them.

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- Severe skin reactions including rash, light sensitivity, blistering or wheals:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin in more than 30% of the body surface (toxic epidermal necrolysis) (very rare)
 - skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme) (very rare)
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- Severe reduction in the number of all types of blood cells, including red and white blood cells as well as platelets (anaemia pancytopenia) (not known)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish spots under the skin surface (signs of blood vessel inflammation) (vasculitis) (not known)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation) (pancreatitis) (not known)
- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible signs of muscle breakdown) (rhabdomyolysis) (not known)

The side effects listed below have also been reported.

Very common – may affect more than 1 in 10 people:

- Loss of appetite
- Stomach problems such as pain, indigestion, feeling full or bloated
- Diarrhoea
- Nausea
- Itching, rash or swelling (rash, urticaria)
- Pains in the muscles and joints (myalgia and arthralgia)

Common – may affect up to 1 in 10 people:

- Headache

Uncommon – may affect up to 1 in 100 people:

- Anxiety or symptoms of depression as a result of taste disturbances (hypogeusia)
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Rare – may affect up to 1 in 1,000 people:

- General feeling of being unwell (malaise)
- Numbness or tingling (paraesthesia, hypoaesthesia)
- Cases of serious hepatic dysfunction, including hepatic failure, hepatic enzymes increased, jaundice, cholestasis and hepatitis.

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

- A feeling of dizziness or “spinning” (vertigo)
- Hair loss (alopecia)
- Menstrual disturbance, bleeding or spotting experienced between menstrual periods or during pregnancy
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