

**PACKAGE LEAFLET:
INFORMATION FOR THE USER
Terbinafine 125mg & 250mg Tablets**

Read all of this leaflet carefully before you start taking this medicine:

- 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 symptoms are the same as yours.

In this leaflet:

1. What Terbinafine Tablets are and what they are used for
2. Before you take Terbinafine Tablets
3. How to take Terbinafine Tablets
4. Possible side effects
5. How to store Terbinafine Tablets
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1. What Terbinafine Tablets are and what they are used for

Terbinafine is an antifungal medicine used to treat fungal skin and nail infections.

2. Before you take Terbinafine Tablets

Do not take Terbinafine Tablets if you

- are **allergic** to terbinafine or any of the other ingredients in Terbinafine Tablets (see section 6)
- have **severe liver** or **kidney** problems
- are **pregnant**, or planning to become pregnant.

Take special care with Terbinafine Tablets and consult your doctor if you have:

- **liver** problems or a disease which may affect your liver
- **kidney** problems or a disease which may affect your kidneys
- **psoriasis**, as taking Terbinafine Tablets may make psoriasis worse
- a high **fever** or **sore throat**
- **lupus**, as taking Terbinafine Tablets may make lupus worse

Taking other medicines

Tell your doctor if you are taking any of the following, as they may affect the way this medicine or your other medicine works:

- **rifampicin**, an antibiotic used to treat fever and infections
- **cimetidine**, used to treat stomach ulcers or to reduce the amount of acid in your stomach
- **oral contraceptives**. If your periods become irregular or if you have any breakthrough bleeding, then **ask your doctor** if other contraceptives are needed whilst taking this medicine.

- **antidepressants**, e.g. imipramine, nortriptyline, amitriptyline, fluoxetine, paroxetine
- any **beta-blocker** drugs, used to treat heart problems or high blood pressure
- monoamine oxidase type B inhibitors (**MAOIBS**) e.g. selegiline.
- **Warfarin**, a medicine used to thin your blood.

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

Pregnancy and breast-feeding

Do not take Terbinafine Tablets if you are **pregnant**, think you are pregnant or are **breastfeeding**. If you become pregnant whilst taking this medicine, tell your doctor.

Driving and using machines

Terbinafine Tablets may make you feel dizzy or tired. Make sure you are not affected before you drive or operate machinery.

3. How to take Terbinafine Tablets

Take Terbinafine Tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Do not take more than the doctor tells you to.

Swallow the tablet **whole** with water at the same time each day.

Adults

Take 1 Terbinafine 250mg Tablet once daily.

Patients with kidney problems

Take 1 Terbinafine 125mg Tablet once daily.

Children

Terbinafine Tablets are **not recommended for children**.

Length of treatment

Your doctor will tell you how long to take Terbinafine Tablets.

Do not stop taking the tablets even if your infection appears to have cleared. Stopping treatment too soon increases the chance of infection returning.

Skin infections: Take for between 2 to 6 weeks.

Nail infections: Take for between 6 to 12 weeks. For toenail infections, you may need to take the tablets for 26 weeks or longer.

If you take more than you should

If you take more tablets than you should, tell your doctor or the nearest casualty department at once. Take this leaflet or some tablets with you, so your doctor will know what you have taken. You may feel dizzy, sick, have a headache or stomach pain.



If you forget to take Terbinafine Tablets

Take one as soon as you remember unless it is nearly time to take the next one. **Do not take two tablets** to make up for the forgotten one. If you are unsure, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Terbinafine Tablets can sometimes cause unwanted side effects.

Stop taking the tablets and tell your doctor at once or phone the casualty department at your nearest hospital if you have:

- a **severe allergic reaction**: rash, itching, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

This is a serious but **very rare** side effect. You may need urgent medical attention or hospitalisation. It may progress to a serious type of shock which causes dizziness, feeling faint, paleness, restlessness, weak/quick pulse and clammy skin.

Stop taking the tablets and contact your doctor at once if you have any of the following rare reactions:

- severe **sore, peeling or blistering skin, mouth, eyes or genitals** (Stevens-Johnson syndrome).
- **symptoms of liver problems** such as yellowing of the skin, itching, constantly feeling sick, loss of appetite, being sick, tiredness, dark urine, light stools or stomach pain.
- **symptoms of a decrease in the number or changes to blood cells** such as unexplained bruising, a high temperature or repeated colds or sore throat.

Tell your doctor or pharmacist if you notice any of the following side effects, they get worse or if you notice any effects not listed.

Common (occur in less than 1 in 10 people)

- loss of appetite, mild stomach ache, diarrhoea
- feeling sick, bloated or full
- rash or reddening of the skin with itching
- headache, tiredness
- joint or muscle pain, usually with swelling or rash

Uncommon (occur in less than 1 in 100 people)

- taste loss or altered taste which usually disappears when you stop taking these tablets. However, a very small number of people (less than 1 in 10,000), have reported the taste disturbance lasts for some time and as a result they go off their food and lose weight.

Rare (occur in less than 1 in 1000 people)

- dizziness, numbness and tingling (pins and needles), reduced sense of touch

Very rare (occur in less than 1 in 10,000)

- depression and anxiety
- vertigo
- hair loss
- worsening of psoriasis; symptoms are dry possibly itchy red patches with flaky, silver/white scaly skin
- appearance or worsening of existing rash, or red patches of skin
- skin swelling, blistering or weals
- sensitivity to light
- irregular menstrual periods or breakthrough bleeding.

5. How to store Terbinafine Tablets

Keep in the original packaging. Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use after the printed expiry date on the blister, carton or label. The expiry date refers to the last day of that month.

Do not use tablets if you notice **signs of deterioration** such as discolouration or crumbling.

Do not throw away down the drain or with household waste. Ask your pharmacist to dispose of medicine no longer required. These measures will help to protect the environment.

6. Further information

What is in your tablets

The ingredient which makes the tablets work is terbinafine. Other ingredients are magnesium stearate (E470b), colloidal anhydrous silica, hypromellose (E464), microcrystalline cellulose (E460) and croscarmellose sodium (E468).

What your tablets look like and contents of the pack

250 mg: Terbinafine Tablets are round white to off-white flat tablets with a break line on one side. The tablets are marked R250 on the reverse side.

125 mg: Terbinafine Tablets are round white flat tablets with a break line on one side. The tablets are marked R125 on the reverse side.

The tablets are available in: **blister packs** of 14, 28, 42, 56 or 98 tablets or **bottles** of 60 or 500 tablets. Terbinafine 125mg Tablets are also available in bottles of 100 tablets.

Marketing authorisation holder and manufacturer

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HU17 0LD

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