

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

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

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 this medicine listed in section 6
- if you have or have had any liver problems
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Terbinafine Tablets. If the answer to any of these questions is YES, Terbinafine Tablets might not be the right medicine for you.

- Are you **pregnant** or **trying to become pregnant**?
- Do you have any problems with your **kidneys** or **liver**?
- Do you have **psoriasis**?
- Do you have **systemic lupus erythematosus (SLE)**?
- Do you have a **rash** due to a high level of a specific type of white blood cells?

Children and adolescents

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.

Some medicines can interfere with your treatment. Tell your doctor if you are taking any of the following:

- **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
- **beta-blockers** or **anti-arrhythmics** for heart problems
- **warfarin**, a medicine used to thin your blood
- medicines used to treat heart problems (e.g. **propafenone**, **amiodarone**)
- **ciclosporin**, a medicine used to control your body's immune system in order to prevent rejection of transplanted organs
- medicines used to treat fungal infections (e.g. **fluconazole**, **ketoconazole**)
- medicines used to treat cough (e.g. **dextromethorphan**)
- **caffeine**.

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

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.

3. How to take Terbinafine Tablets

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

The usual dose for adults, including the elderly is 250 mg once a day.

- For skin infections continue taking the tablets for **2 to 6 weeks**.
- For nail infections treatment usually lasts for between **6 weeks and 3 months**, although some patients with toenail infections may need to be treated for **6 months or longer**.
- If your kidneys are not working very well, your doctor may reduce the dose of Terbinafine Tablets you take.
- Swallow the tablets/tablet halves whole with a glass of water.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

If you take more Terbinafine Tablets than you should

All tablets can be risky if you take too many. If you take too many Terbinafine Tablets at once, tell your doctor or hospital casualty department as soon as possible. Take your medicine pack with you so that people can see what you have taken.

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.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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:

- 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 problems), increase in liver enzymes which may be noted on a blood test result
- severe skin reactions including rash, light sensitivity, blistering or wheals
- 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)
- difficulty 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)

The most common side effects are:

- headache
- stomach problems such as loss of appetite, ache, indigestion, feeling bloated or sick
- diarrhoea
- itching, rash or swelling
- pains in the muscles and joints

The side effects listed below have also been reported.

Uncommon (may affect up to 1 in 100 people)

- taste loss and taste disturbance. This usually disappears within several weeks after you stop taking this 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)

- feeling unwell, dizzy
- numbness or tingling.

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

- feeling tired, decrease in the number of some blood cells. You may notice that you seem to bleed or bruise more easily than normal, or you may catch infections easily and these might be more severe than usual
- psoriasis like skin eruptions, or worsening of any psoriasis including a rash or eruption of small pus containing blisters
- vertigo

- hair loss
- onset or worsening of a condition called lupus (a long-term illness with symptoms including skin rash and pain in the muscles and joints).

Frequency not known (frequency cannot be estimated from the available data)

- Signs of blood disorders: weakness, unusual bleeding, bruising or frequent infections.
- Disorders of sense of smell which may be permanent, impaired hearing, hissing and/or ringing in the ears, flu like symptoms, increase in blood of a muscle enzyme called creatine phosphokinase (may be found on a blood test), reduced or blurred vision.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Terbinafine Tablets

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

Do not store above 25°C.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use. 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.

Terbinafine 250 mg Tablets contain 250 mg of the active ingredient terbinafine.

Terbinafine 250 mg Tablets also contain the inactive ingredients magnesium stearate (E470b), colloidal anhydrous silica, hypromellose (E464), microcrystalline cellulose (E460) and croscarmellose sodium (E468).

What Terbinafine Tablets look like and contents of the pack

Terbinafine 250 mg 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.

The tablets are available in: **blister packs** of 14, or 28 tablets or **bottles** of 60, 100 or 500 tablets. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Dr Reddy's Laboratories (UK) Ltd
6 Riverview Road, Beverley, East Yorkshire.
HU17 0LD

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