

Terbinafine 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.
- 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.

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1 What Terbinafine tablets are and what they are used for

Terbinafine belongs to a group of medicines called antifungal drugs. Terbinafine tablets are used for the treatment of fungal infections of:

- the groin area.
- the skin (ringworm).
- toe and finger nails (yellow, opaque and thickened nails).
- the feet (athlete's foot).

2 Before you take Terbinafine tablets

Do not take Terbinafine tablets and **tell your doctor** if you:

- are **allergic** (hypersensitive) to terbinafine (active substance) or any of the other ingredients of Terbinafine tablets (see section 6).
- suffer from severely impaired **liver** or **kidney** function.

Check with your doctor or pharmacist before taking Terbinafine tablets if you:

- have an **autoimmune disease** e.g. systemic lupus erythematosus.
- suffer from **liver** disease.
- suffer from **psoriasis** (scaling skin disease), as it may worsen whilst you are taking Terbinafine tablets.

- Fungal infection of the nails:

Fingernails: 250mg (one 250mg Terbinafine tablet) once a day for 6 weeks.

Toenails: 250mg (one 250mg Terbinafine tablet) once a day for 12 weeks. Some cases may require treatment for up to 6 months.

Complete healing of the infection may not occur until several weeks after completing the course of treatment. A healthy nail may take several months to grow back.

- **Children:**
Use in children is not recommended.
- **Impaired kidney function:**
If you have impaired kidney function, your doctor may prescribe you a lower dose. Please follow your doctor's instructions.

If you take more Terbinafine tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include headache, feeling sick, pain in the upper part of the stomach (epigastric pain) and dizziness.

If you forget to take Terbinafine tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

4 Possible side effects

Like all medicines, Terbinafine tablets can cause side effects, although not everybody gets them.

Contact your doctor immediately if you develop:

- **impaired liver function** including yellowing of the skin or whites of the eyes (jaundice), inflammation of the liver (hepatitis) and blocked bile flow (cholestasis). Symptoms include itching, constantly feeling sick, loss of appetite, tiredness, being sick, fatigue, stomach pain, dark urine or pale stools.
- **an allergic (hypersensitivity) reaction** with swelling of the face, lips, tongue or throat, difficulty breathing or swallowing (anaphylaxis) or skin reactions such as a rash or pale or red irregular raised patches with severe itching (hives).
- **a skin reaction** such as a severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), sensitivity to sunlight or artificial light (e.g. sun beds).
- fever or sore throat.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common (they occur in between 1 and 10 per 100 patients who receive treatment)

Headache, feeling of fullness, loss of appetite, indigestion, feeling sick, mild stomach pain, diarrhoea.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- rifampicin (an antibiotic).
- cimetidine (used to treat stomach ulcers).
- tricyclic antidepressants, selective serotonin reuptake inhibitors and monoamine oxidase inhibitors (medicines for depression).
- beta blockers (heart medicines).
- ciclosporin (used to prevent and treat the rejection of transplants and also used in immune diseases).
- tolbutamine (used for diabetes).
- terfenadine (an antihistamine).
- triazolam (a sedative).
- oral contraceptives. Break-through bleeding and irregular periods may occur when Terbinafine tablets are taken with oral contraceptives.
- Warfarin (used to thin the blood).

Pregnancy and breast-feeding

If you are breast-feeding, you should not take Terbinafine tablets. If you are pregnant or planning to become pregnant, you should not take Terbinafine tablets unless your doctor decides it is necessary. You must only take Terbinafine tablets according to your doctor's instructions.

Driving and using machines

Terbinafine tablets may affect your ability to drive or operate machines.

3 How to take Terbinafine tablets

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

Swallow the tablets **with water**.

The usual dose is

- **Adults (including the elderly):**
Duration of treatment depends on the type of fungal infection and the severity of the infection.
- Fungal infection of the groin area, skin and feet: 250mg (one 250mg Terbinafine tablet) once a day for 2-4 weeks. Some cases of athlete's foot may require treatment for up to 6 weeks.

Complete healing of the infection may not occur until several weeks after completing the course of treatment.

Uncommon (they occur in between 1 and 10 per 1,000 patients who receive treatment)

Taste disturbances and loss of taste sense.

Rare (they occur in between 1 to 10 per 10,000 patients who receive treatment)

'Pins and needles' or tingling, reduced sense of touch, dizziness, a feeling of general discomfort and illness, tiredness, joint pain (arthralgia), muscle pain (myalgia).

Very rare (they occur in less than 1 per 10,000 patients who receive treatment, including isolated reports)

Changes in the blood count, if you notice increased bruising, nosebleeds, sore throats or infections you should tell your doctor who may want you to have a blood test. Worsening of psoriasis (scaling skin disease), loss of hair, development or worsening of severe immune disease with skin symptoms (systemic lupus erythematosus), psychiatric symptoms such as depression and anxiety.

Not known (frequency can not be estimated from the available data)

Skin rash with blisters and fever (Acute generalised exanthematous pustulosis (AGEP)).

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.

5 How to store Terbinafine tablets

Keep out of the reach and sight of children.

Keep the blister in the outer carton.

Do not use Terbinafine tablets after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month. 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 Further information

What Terbinafine tablets contain

- The active substance is terbinafine as terbinafine hydrochloride. Each tablet contains 250mg of the active substance.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, silica colloidal anhydrous, hypromellose and magnesium stearate.

What Terbinafine tablets look like and contents of the pack

Terbinafine tablets are white, round, flat tablets. Terbinafine tablets are available in the following pack sizes: 14 and 28.