

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.

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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 (ring worm).
- Toe and finger nails (yellow, opaque and thickened nails).
- The feet (athlete's foot).

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).
- suffer from severely impaired **liver** or **kidney** function.

Warnings and precautions

Talk to your doctor or pharmacist before taking Terbinafine tablets if you:

- suffer from **liver** disease.
- suffer from **kidney** disease.
- suffer from **psoriasis** (scaling skin disease) or **lupus erythematosus** (auto-immune disorder, affecting the skin, joints, kidneys & brain) , as it may worsen whilst you are taking Terbinafine tablets.

Children and adolescents

Use in children is not recommended.

Other medicines and Terbinafine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to tell your doctor about the following:

- Rifampicin (an antibiotic).
- Cimetidine (used to treat stomach ulcers).
- Tricyclic antidepressants, selective serotonin reuptake inhibitors and monoamine oxidase inhibitors (medicines for depression).
- Amiodarone, beta blockers, other antiarrhythmic drugs (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.
- Fluconazole, ketoconazole (used to treat fungal infections)
- Caffeine

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

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

Swallow the tablets **with water**.

The recommended 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.

- 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.

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

You must contact your doctor immediately if you notice any of the following:

- **Impaired liver function or liver failure** including reduction in liver enzymes (seen in tests), 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), circular, irregular red patches on the skin of the hands and arms (erythema multiforme), 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:

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

- Loss of appetite,
- Feeling of fullness,
- Indigestion,
- Feeling sick,
- Mild stomach pain,
- Diarrhoea,
- Joint pain (arthralgia),
- Muscle pain (myalgia)

Common (may affect up to 1 in 10 people)

- Headache

Uncommon (may affect up to 1 in 10 people)

- Taste disturbances and loss of taste sense

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

- A feeling of general discomfort and illness

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

- 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),
- Tiredness,
- Dizziness,
- 'Pins and needles' or tingling,
- Reduced sense of touch,
- Skin rash with blisters and fever (Acute generalised exanthematous pustulosis (AGEP)).

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

- Reduction of red blood cells (anaemia) which can make the skin pale and cause weakness or breathlessness,
- Rash, fever joint pain and enlarged lymph nodes (serum sickness),
- Psychiatric symptoms such as depression and anxiety.
- Lack of sense of smell,
- Slight deafness or impaired hearing, ringing or buzzing in the ears,
- Rash,
- Fever,
- Sweating,
- Fatigue,
- Weight loss (caused by inflammation of the blood vessels),
- Inflammation of the pancreas causing pain and tiredness in the abdomen and back,

- Abnormal muscle breakdown which can lead to kidney problems,
- Flu like symptoms,
- Increase or decrease in weight and an increase in creatinine levels in the blood (seen in tests)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 out of the sight and reach of children. This medicine does not require any special storage conditions.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help 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, anhydrous colloidal silica, hypromellose and magnesium stearate.

What Terbinafine tablets look like and contents of the pack

Terbinafine tablets are white, round, flat tablets, scored on both sides with side scores and marked with 'T' above and '1' below the score on one side. Terbinafine tablets are available in the following blister pack sizes: 14 and 28.

Marketing Authorisation Holder and Manufacturer:

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in October 2016.