

PATIENT INFORMATION LEAFLET
TERBINAFORCE Tablets

Terbinafine 250 mg tablets

Read all of this leaflet carefully before you start using this medication 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.

1. What is TERBINAFORCE and what it is used for
TERBINAFORCE belongs to a group of medicines called antifungal drugs, used for the treatment of fungal infections of the skin and nails such as treatment of ringworm (tinea corporis, tinea cruris and tinea pedis) where oral therapy is considered appropriate due to the site, severity or extent of the infection and treatment of onychomycosis (ATC code: D01BA02).

2. What you need to know before you take TERBINAFORCE Tablets

Do not take TERBINAFORCE Tablets if you are allergic (hypersensitive) to terbinafine or to any of the other ingredients (listed in section 6) or if you suffer from severely impaired liver or kidney function.

Take special care with TERBINAFORCE Tablets if you suffer from liver or kidney disease; 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 TERBINAFORCE Tablets.

Pregnancy and breast-feeding: if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not take TERBINAFORCE Tablets, unless your doctor decides it is necessary.

Taking other medicines: Always tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This means medicines you have bought yourself as well as medicines on prescription from your doctor. It is especially important to tell your doctor about the following: Rifampicin (an antibiotic); Cimetidine (to treat stomach ulcers); antidepressants such as tricyclic antidepressants, selective serotonin reuptake inhibitors and monoamine oxidase inhibitors; Triazolam (a sedative); Amiodarone, beta blockers, other antiarrhythmic drugs (heart medicines); Warfarin (to thin your blood); Ciclosporin (to prevent and treat the rejection of transplants and also used in immune diseases); Tolbutamide (for diabetes); Terfenadine (an antihistamine); oral contraceptives; Fluconazole, Ketoconazole (to treat fungal infections); Caffeine.

Driving or using machinery: some people have reported feeling dizzy or giddy while they are taking TERBINAFORCE Tablets. If you feel like this you should not drive or operate machinery.

3. How to take TERBINAFORCE 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. Do not exceed the recommended dose.

• **Adults:** 250 mg daily = 1 TERBINAFORCE 250 mg Tablet once daily

• **Children:** Not recommended

The duration of treatment varies according to the indication and the severity of the infection:

Skin Infections

Likely duration of treatment are as follows:

Tinea pedis (interdigital, plantar/moccoasin type):	2 to 6 weeks
Tinea corporis:	4 weeks
Tinea cruris:	2 to 4 weeks

Onychomycosis

For most patients the duration of treatment is between 6 weeks and 3 months although treatment periods of less than 3 months can be anticipated in younger patients or those with fingernail infections or toenail infections other than the big toe. 3 months is usually sufficient in the treatment of toenail infections although some patients may require 6 months treatment or longer. Poor nail outgrowth during the first weeks of treatment may indicate those patients where longer therapy is required. The complete resolution of signs and symptoms of infection may not occur until several weeks after mycological cure.

If you take more TERBINAFORCE Tablets than you should, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include headache, nausea, epigastric pain and dizziness.

If you forget to take a TERBINAFORCE Tablets, take it as soon as you remember it and then take the next dose at the right time (do not take a double dose to make up for a forgotten dose).

4. Possible side effects

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

Contact your doctor immediately if you notice any of the following:

Impaired liver function or liver failure including reduction in liver enzymes, yellowing of the skin or white of the eyes, inflammation of the liver and blocked bile flow. 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 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, severe rash involving reddening, peeling and swelling of the skin resembling severe burns, circular, irregular red patches on the skin of the hands and arms, sensitivity to sunlight or artificial light. **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** (more than 1 in 10 people): loss of appetite, feeling of fullness, indigestion, feeling sick, mild stomach pain, diarrhoea, joint pain, muscle pain. **Common** (up to 1 in 10 people): headache. **Uncommon** (up to 1 in 100 people): taste disturbances and loss of taste sense. **Rare** (up to 1 in 1,000 people): feeling of general discomfort and illness. **Very rare** (up to 1 in 10,000 people): changes in the blood count (increased bruising, nosebleeds, sore throats or infections), worsening of psoriasis (scaling skin disease), hair loss, 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. **Not known:** reduction of red blood cells which can make the skin pale and cause weakness or breathlessness, rash, fever joint pain and enlarged lymph nodes, psychiatric symptoms (depression and anxiety), lack of sense of smell, impaired hearing, ringing or buzzing in the ears, rash, fever, sweating, fatigue, weight loss, 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).

5. How to store TERBINAFORCE Tablets: Do not store above 30°C, in the original package, protected from light and/or moisture. Keep all medicines out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

6. Other information

What TERBINAFORCE Tablets contains:

250 mg Terbinafine (as 281.25 mg Terbinafine Hydrochloride). **Other ingredients:** Microcrystalline Cellulose, Sodium Starch Glycolate, Hydroxypropyl Methyl Cellulose (E-5), Colloidal Silicon Dioxide, Magnesium Stearate and Purified Water.

TERBINAFORCE Tablets are White to off-white coloured, round, biconvex, uncoated tablets, plain on both sides.

They come in blister packs of 30 tablets i.e. 10 tablets packed in one blister. Three such blisters are packed in a carton).

TERBINAFORCE Tablets is a prescription only medicine.

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