Package Leaflet: Information for the Patient

Terbinafine 250 mg Tablets
(Terbinafine)

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 symptoms 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.

The name of your medicine is Terbinafine 250 mg Tablets. In the rest of this leaflet it is called Terbinafine Tablets.

What is in this leaflet:

1. What Terbinafine Tablets are and what they are used for

Terbinafine belongs to a group of medicines called antifungals. Terbinafine Tablets are used to treat a variety of fungal skin and nail infections.

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

Do not take Terbinafine:

- if you are allergic to terbinafine hydrochloride or any of the other ingredients of Terbinafine Tablets.
- if you have or have had any liver problems.
- if you are breast-feeding

Warning and precautions

Tell your doctor *or* pharmacist before you take Terbinafine Tablets:

- if you are pregnant or trying to become pregnant
- if you have any problems with your kidneys or liver
- if you have psoriasis
- if you have systemic lupus erythematosis (SLE)
- if you have rash due to a high level of a specific type of white blood cells

Children
Terbinafine Tablets are not recommended in children.

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 for infections
- Cimetidine for gastric problems such as indigestion or ulcer
- Antidepressants including tricyclic antidepressants, SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)
- Oral contraceptives (as irregular periods and breakthrough bleeding may occur in some female patients)
- Beta-blockers or anti-arrhythmics for heart problems
- Warfarin, a medicine used to thin your blood
- Medicines to treat heart problems (eg 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 (eg fluconazole, ketoconazole)
- Medicines used to treat cough (eg dextromethorphan)
- Caffeine

Always tell your doctor or pharmacist about all medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

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

Taking Terbinafine with food and drink
It does not matter when you take your Terbinafine Tablets in relation to food.

Pregnancy and breast-feeding

- If you are pregnant or breast feeding, think you may be pregnant or you are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.
- Terbinafine should not be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risks of taking Terbinafine during pregnancy.
- Do not take Terbinafine Tablets if you are breast-feeding
- Ask your doctor or pharmacist for advice before taking any medicine.

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

The recommended dose is one 250 mg tablet a day. If your kidneys are not working very well, your doctor may reduce the dose of Terbinafine Tablets you take.

Do not remove the tablet from the blister until you are ready to take it. To obtain a tablet, press on the tablet from the blister (or bubble) side, pushing it through the foil. Unless told otherwise, you should swallow your tablets whole with water.

The length of treatment will depend upon your condition. For skin infections, this is usually two to six weeks. For nail infections this is usually six weeks to three months - some patients with a toe nail infection may need longer treatment.

Do not stop taking the medicine without talking to your doctor first.
If you have any further questions on the use of Terbinafine Tablets, ask your doctor or pharmacist.

If you take more Terbinafine than you should
If you take too many tablets, you may feel sick or suffer headache, stomach pain or dizziness. You should contact your doctor or pharmacist, or go to the nearest hospital casualty department immediately. Take this leaflet and any tablets you have left to show, the doctor or pharmacist.

If you forget to take Terbinafine
Do not take a double dose to make up for a forgotten tablet. If you forget to take a dose do not worry, just take the next dose when it is due.

4. Possible side effects

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

<u>Some side effects can be serious</u>
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 might indicate liver problems), increase in liver enzymes which may be noted on a blood test results
- 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 might be sign of blood disorders)

(continued over)

FPO

- 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 break down)

The side effects listed below have also been reported.

Very common: may affect more than 1 in 10 people
- Stomach problems such as loss of appetite, ache, indigestion, feeling bloated or sick
- Diarrhoea
- Itching, rash or swelling
- Pain in the muscles and joints

Common: may affect up to 1 in 10 people
- Headache

Uncommon: may affect up to 1 in 100 people:
Taste loss or taste disturbance. This usually disappears within several weeks after you stop taking the 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 and 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)

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.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

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 national reporting systems listed below:

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:
HPRA Pharmacovigilance; Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

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

5. How to store Terbinafine Tablets

Keep this medicine out of the sight and reach of children.
Do not use Terbinafine Tablets after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
Keep the blister in the outer carton in order to protect from light.
Do not use Terbinafine Tablets if they are discoloured (they should be white to offwhite).
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. Contents of the pack and other information

What Terbinafine contains
- The active substance is terbinafine. Each tablet contains terbinafine hydrochloride, equivalent to 250 mg of terbinafine.
- The other ingredients are microcrystalline cellulose, colloidal silica anhydrous, hypromellose, sodium starch glycollate Type A and magnesium stearate.

What Terbinafine looks like and contents of the pack

Terbinafine Tablets are white to off-white tablets with a 'T' on one side and score line on the reverse. The tablet can be divided into equal halves.

They come in blister packs containing 7, 14, 28, 30 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Other sources of information:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)

Please be ready to give the following information:

Product Name	Reference Number
Terbinafine 250mg Tablets	PL 29831/0197

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland please call +44 1978 661 261.

This medicinal product is authorised in the Member States of the EEA under the following names:
United Kingdom and Ireland: Terbinafine 250mg Tablets

This leaflet was last revised in 01/2018.

WOCKHARDT