

PATIENT INFORMATION LEAFLET

TERBISIL® 250 mg tablet **For oral use.**

- **Active substance:** Each tablet contains 281.25 mg terbinafine hydrochloride, equivalent to 250 mg terbinafine
- **Excipients:** Colloidal silicone dioxide, magnesium stearate, hydroxypropyl methyl cellulose, microcrystalline cellulose, and sodium starch glycolate.

Please read this PATIENT INFORMATION LEAFLET carefully before you start to take your medicine as it may contain 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.*
- *Tell your doctor that you are currently being treated with this medicine if you seek medical assistance from a doctor or a hospital*
- *Follow these instructions closely. Do not take higher or lower doses than the one prescribed for you.*

IN THIS LEAFLET you can find the following information:

- 1. What TERBISIL® is and what is it used for***
- 2. Before you take TERBISIL®***
- 3. How to take TERBISIL®***
- 4. Possible side effects***
- 5. How to store TERBISIL®***
- 6. Further information***

1. What TERBISIL® is and what is it used for?

TERBISIL® is presented in blister packs of 14 and 28 tablets. The tablets are white or yellowish-white, round, slightly biconvex tablets. Scored on one side with T₂₅ logo

TERBISIL® tablets contain terbinafine hydrochloride as the active ingredient that belongs to antifungal class of medications.

TERBISIL® tablets are used for the treatment of fungal toenail and finger nail infections, yeast infections of the skin, and tinea infections in the scalp, hair, groins, in other regions of the body, and in the feet (Athlete's foot).

When taken orally, terbinafine reaches concentrations high enough to kill or to stop the growth of fungi at the site of infection.

2. What you need to know before you take TERBISIL®

Do not take TERBISIL®

If;

- You are allergic (hypersensitive) to TERBISIL® or any of the other ingredients of this medicine listed at the beginning of this instructions for use.

- If you had in the past or currently have liver problems.
- If you have any kidney problems.

CARE SHOULD BE TAKEN when you use TERBISIL[®]

If:

- You are using other medications (see. Use with other medicines).
- You have unexplained persistent nausea, vomiting, abdominal pain, loss of appetite, unusual fatigue; yellow discoloration in the skin or eye; darkening in the urine color or pale stools (signs of liver problems). Your doctor may perform blood tests to monitor your liver functions before or after you start treatment with TERBISIL[®]. You may have to stop TERBISIL[®] if you have abnormal results.
- You have rashes, redness, vesicles in the lips, eyes, or mouth, skin problems such as desquamation, fever (possible symptoms of severe skin reactions), elevated numbers of a specific white blood cell type leading to skin desquamation (eosinophilia);
- You have thick reddish/pearl-gray patches (Psoriasis) or rashes in the skin, joint pain, muscle discomfort, and high fever (cutaneous or systemic lupus erythematosus).
- You have fatigue, unexpected bleeding, bruising, or frequent infections (symptoms of blood problems);
- You are currently or have recently taken any other medications, please refer to the section on “Use with other medicines”.

If any of the above apply to you or has ever applied to you please talk to your doctor.

TERBISIL[®] with food and drink

TERBISIL[®] tablets can be taken regardless of the meal time.

Pregnancy

Talk to your doctor or pharmacist before you take this medicine.

Your doctor will discuss the potential risks of using TERBISIL during pregnancy.

If you are pregnant or think that you are pregnant, talk to your doctor.

Unless specifically recommended by your doctor, you should not use TERBISIL during pregnancy.

If you become pregnant during your treatment, contact with your doctor or pharmacist immediately.

Breastfeeding

Please consult with your doctor or pharmacist before taking this medicine.

You should not breast-feed during lactation since your baby may be exposed to TERBISIL. This may harm your baby.

Driving and using machines

If you feel drowsy when you are taking TERBISIL tablets, you should not drive or use machinery.

Important information on some of the excipients of TERBISIL[®]

If you do not have hypersensitivity to any of the excipients in TERBISIL, adverse effects due to these ingredients are unlikely.

Use with other medications:

Tell your doctor if you are using:

- Certain medications used for the treatment of infectious diseases that are termed as antibiotics (e.g. rifampicin)
- Caffeine
- Certain medications used for the treatment of mood disorders (tricyclic antidepressants, selective serotonin reuptake inhibitors including class 1A, 1B, and 1C, monoamine oxidase inhibitor Type B, and antidepressants such as desipramine).
- Medications used for the treatment of cardiac rhythm disturbances (anti-arrhythmic such as propafenone, amiodarone)
- Medications used for the treatment of high blood pressure (certain beta-blockers such as metoprolol)
- Certain medications used for the treatment of stomach ulcers (e.g. cimetidine)
- Certain medications used for the treatment of fungal infections (e.g. fluconazole, ketoconazole)
- Medications used for the treatment of cough (e.g. dextromethorphan)
- A medication called cyclosporine, which is used to control your immune system to prevent rejection of transplanted organs.
- Warfarin, a blood thinning agent.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

3. How to take TERBISIL®?**Instructions for appropriate use and dosage/administration frequency**

Always take this medicine exactly as your doctor has told you. If you have an impression that TERBISIL®'s effect is much stronger or weaker than expected, talk to your doctor or pharmacist.

Adults:

Normal dose is a single 250 mg tablet once daily.

Children:

There is no experience with TERBISIL® use in children under 2 years of age (bodyweight generally less than 12 kg)

The dosage in children ≥ 2 years of age the dosage is adjusted according to the bodyweight.

In children with a bodyweight between 20 and 40 kg: 125 mg once daily (1/2 tablet TERBISIL)

In children with a bodyweight > 40 kg: 250 mg once daily (1 tablet TERBISIL®)

When to take TERBISIL®?

Take your medicine at about the same time everyday to remember your treatment plan.

How long should TERBISIL® be used?

This depends on the type, severity, and site of the infection. Your doctor will tell you exactly how long to take your tablets.

Normal treatment duration is as follows:

For fungal infections of the foot (Tinea) (Athlete's foot), TERBISIL® is generally used for 2 to 6 weeks.

Fungal infection of the groins or other body sites (Tinea) and in yeast infections, TERBISIL® is generally taken for 2 to 4 weeks.

It is important that you take your tablet(s) everyday as long as your doctor has told you to do so. This will ensure that infection will be completely cleared and the risk of recurrence will be minimized.

Hair and scalp infections:

For fungal infections of the scalp and hair (Tinea) the normal duration of treatment is 4 weeks.

Nail infections:

Fungal infections of the nails generally heal much more slowly than fungal infections of the skin. For most of the nail infections, TERBISIL® tablets should be taken for 6 to 12 weeks.

Fingernail infections:

A 6 week treatment course is adequate for most cases.

Toenail infections:

A 12 week treatment course is adequate for most cases.

A longer duration of treatment may be needed in patients with inadequate nail growth. Your doctor will discuss this with you.

The route and method of administration

TERBISIL® tablets are to be taken by mouth. You can take TERBISIL® irrespective of the meals. Swallow the tablet with one glass of water.

There are other steps that you can take to help clear up your infection and make sure that it does not return. For example, keep the infected area dry and cool and change clothing that it is in direct contact with the infected area daily.

Age groups

Use in children and adolescents (between 2 and 17 years of age):

TERBISIL® tablets can be used in adolescents and children over 2 years of age. Your doctor will adjust the dose according to age and bodyweight.

TERBISIL® tablets are not recommended in children under 2 years of age, as there is no clinical experience in this age group.

Use in elderly (≥ 65 y)

If you are 65 years or older, you can take the same dose of TERBISIL[®] as younger individuals. Patients in this age group should be assessed with regard to potential liver or kidney dysfunction. A potential pre-existing liver or kidney problem should be considered when prescribing TERBISIL[®] tablets to elderly individuals.

Special precautions for use**Liver/kidney failure**

If you have had or currently have liver problems or renal problems, use of TERBISIL[®] is not recommended.

Follow these instructions unless recommended otherwise by your doctor.

Your doctor will tell you how long to take TERBISIL[®]. Do not prematurely stop your treatment, as stopping TERBISIL[®] treatment may worsen your condition.

If you have the impression that TERBISIL[®]'s effect is much stronger or weaker than expected, talk to your doctor or pharmacist.

If you take more TERBISIL[®] than you should

If you have taken more TERBISIL[®] than you should, talk to your doctor or pharmacist.

If you accidentally take more tablets than prescribed by your doctor, immediately call your doctor or a hospital for advice. You may require medical treatment. That also applies to others who have accidentally taken your medicine. Symptoms associated with TERBISIL[®] overdosing include headache, sickness, stomach pain, or dizziness.

What if you forget to take TERBISIL[®]

Take it as soon as you remember, unless it is less than 4 hours before your next dose is due. In this case, wait and take your next tablet at the usual time. Then carry on as normal until you have finished all the tablets. Do not take a double dose to make up for a forgotten dose.

Possible effects upon stopping treatment with TERBISIL[®]

Stopping treatment with TERBISIL[®] may worsen your condition. Do not stop your treatment unless your doctor has told you to do so.

4. What are potential side effects?

As with all other medications, TERBISIL[®] may lead to side effects in subjects who are sensitive to one or more of ingredients.

TERBISIL[®] treatment may result in side effects such as the following:

Stop TERBISIL[®] treatment immediately and talk to your doctor or seek for emergent medical assistance.

- TERBISIL[®] may rarely cause liver problems, which can be severe in very rare cases.
- Very rare cases of decrease in certain blood cell types, autoimmune conditions (a condition affecting the immune system) (Lupus), or severe skin reactions have been reported.

- Inflammation of the blood vessels, inflammation of the pancreas, death of muscular cells.

These represent very severe side effects.

If you have any of these, you may have serious allergy against TERBISIL[®] requiring urgent medical care or hospital admission.

These very severe side effects occur rarely.

Stop taking the tablets and tell your doctor immediately if you notice any of the following symptoms:

- Unexplained persistent nausea, stomach problems, loss of appetite, abnormal fatigue, or weakness.
- Yellowing of your skin or eyes. Unusually dark urine or pale faces, (this may indicate liver problems)
- Fever, chills, sore throat or oral ulcers and fatigue due to infections, or increased frequency of infections.
- Unexpected bleeding or bruises (possible signs of a condition of a certain type of blood cells).
- Difficulty in breathing, dizziness, swelling particularly in the throat and face, hot flushes, high fever or lymph node swelling/enlargement (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)
- Rash or redness of the skin, blisters on the lips, eyes, or mouth, skin desquamation and fever
- Severe upper stomach pain which spreads to the back (possible signs of pancreas)
- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible breakdown of muscle cells).

These are all serious side effects that require urgent medical attention.

Talk to your doctor if you notice any of the following:

The frequency of side effects is categorized as below:

Very common:	$\geq 1/10$ patients
Common:	$< 1/10$ and $\geq 1/100$ patients
Uncommon:	$< 1/100$ and $\geq 1/1000$ patients
Rare:	$< 1/1000$ patients
Very rare:	$< 1/10000$ patients
Frequency unknown:	Occurring in very few patients, precluding a frequency analysis

Very common:

- Headache
- Nausea
- Mild stomach pain
- Indigestion after meals (heartburn)
- Diarrhea

- Bloating or gas in the stomach
- Loss of appetite
- Rashes (itchy)
- Joint and muscle pain

Common:

- Mood disorder (depression)
- Loss of change in taste sensation
- Dizziness
- Eye disorder
- Fatigue

Uncommon:

- Abnormally pale skin, mucosal tissue, or nail beds
- Unusual fatigue or weakness or shortness of breath upon exertion (possible signs of a condition affecting red blood cells)
- Anxiety
- Tingling, numbness, or decreased sense of touch in the skin
- Hypersensitivity to sunlight
- Abnormal hearing (e.g. a whispering sound)
- High fever
- Loss of weight

Rare

- Yellowish discoloration in the eye or skin (liver problems); abnormal liver function tests

Very rare:

- Reduced numbers of certain blood cells
- Lupus (an immune system disorder)
- Severe skin reactions
- Allergic reactions
- Psoriasis-like skin rashes (pearl-gray rashes)
- Worsening of psoriasis
- Skin desquamation with scales
- Hair loss

Also the following side effects have been reported:

- Severe allergic reactions or infections
- Inflammation of the blood vessels
- Disorders of the sense of smell (e.g. permanent decrease in the sense of smell)
- Decreased ability to smell
- Blurred vision, decreased visual acuity
- Inflammation of the pancreas
- Skin rash due to increased numbers of a specific type of white blood cell
- Death of muscle cells

- Flu like symptoms (e.g. fatigue, chills, sore throat, joint or muscle pain)
- Increased concentration of a muscle enzyme (creatinine phosphokinase).

If you have any side effects not listed in this brochure talk to your doctor or pharmacist.

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. How to store TERBISIL®

Keep TERBISIL® out of the reach and sight of children in its original packing.

Protect from light.

Store in room temperature below 30°C.

Check the expiry date on the pack

Do not use TERBISIL® after the expiry date printed on the pack.

If you notice any compromise in the product and/or its packing, do not use TERBISIL®.

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These package information leaflet have been approved on 23 Sep 2013.