PACKAGE LEAFLET: Information for the user

TERBIDERM

Tablets – 250 mg

Terbinafine hydrochloride

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 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 or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

In this leaflet:

1. WHAT TERBIDERM IS AND WHAT IT IS USED FOR?

Terbiderm 250 mg contains the active substance terbinafine hydrochloride, which is a drug that acts against fungal infections (antifungal).

Terbiderm is indicated in:

- fungal infections of the fingernails and toenails (distal-subungual onychomycosis) caused by dermatophytes; in mixed infections of the nails with distal-subungual type mycosis, an experimental treatment is applied;
- severe, resistant fungal infections of the feet (tinea pedis) and body (tinea corporis and tinea cruris), caused by dermatophytes and that are not adequately treated by topical therapy.

Note:

To confirm the diagnosis, it is recommended to take appropriate skin or nail specimens for laboratory testing (KOH preparation, fungal culture or nail biopsy) before starting treatment with Terbiderm 250 mg. In contrast to locally used terbinafine, Terbiderm is not effective in mycotic infections (candidiasis, pityriasis versicolor) of the skin.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TERBIDERM?

Do not take Terbiderm:

- if you are hypersensitive to terbinafine hydrochloride or to any of the excipients mentioned in section 6;
- if you suffer or have suffered before from an acute or chronic liver disease;
- if you suffer from kidney disease;
- if the nails fungal infection comes as a result of a primary bacterial infection.

Take special care with Terbiderm

Consult with your doctor or pharmacist before taking Terbiderm:

- if you notice symptoms such as: unexplained prolonged nausea, vomiting, abdominal pain, loss of appetite, weight loss, unusual fatigue, yellowing of the skin or of the whites of the eyes, dark urine or pale stools unlike the usual (signs of liver disease); before and periodically during treatment with Terbiderm, your doctor may perform blood tests to check the function of the liver; if there are atypical results of the tests, your doctor may ask you to discontinue the treatment with Terbiderm;
- if you notice skin problems such as: rash, redness, blisters in the lips, eyes or mouth, peeling of the skin, fever (signs of serious skin reactions), rash associated with an increased number of certain white blood cells (eosinophilia);
- if you have or notice psoriasis or lichen in the form of butterfly (lupus erythematosus, an autoimmune disease with face rash), joint pain, muscle disorders and fever (cutaneous or systemic lupus erythematous);
- if you feel weakness or have unusual bleeding, bruising or frequent infections (signs of blood disorders).

If you notice any of these symptoms, **tell your doctor immediately.**

Children

Children should not take Terbiderm because there are limited data for its use in children.

Taking Terbiderm with other medicines

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or are planning to take / use other medicines, including those taken without a prescription.

The effect of Terbiderm can be affected by the concomitant treatment with the drugs or groups of drugs presented below. The doctor may adjust the dose according to the case:

The effect of Terbiderm may be enhanced by the concomitant administration of drugs that inhibit the metabolism of terbinafine hydrochloride [e.g. cimetidine (gastrointestinal agent), fluconazole (antifungal), ketoconazole (antifungal), amiodarone (antiarrhythmic)].

The effect of Terbiderm may be decreased by the concomitant administration of drugs that induce the metabolism of terbinafine hydrochloride [e.g. rifampicin (antibiotic)].

The effect of other drugs can be affected by concomitant treatment with Terbiderm:

Terbiderm may enhance the effect of the following drugs: drugs for the treatment of depression (tricyclic antidepressants, serotonin reuptake inhibitors, type B monoamine oxidase inhibitors, desipramine).

Some drugs for the treatment of high blood pressure (specific beta-blockers, e.g. metoprolol).

Some drugs for the treatment of arrhythmias and cardiovascular disorders (antiarrhythmics, including class 1A, 1B, 1C, e.g.: propafenone, amiodarone), beta-blockers, caffeine, cough medicines (e.g.: dextromethorphan).

Terbiderm may decrease the effect of cyclosporine (a drug used to avoid the rejection of transplanted organs).

Make sure that your doctor is aware if you are taking these drugs or any other drug.

Concomitant administration of Terbiderm with drugs that are metabolised by the same enzymatic system as terbinafine hydrochloride (e.g. terfenadine, triazolam, tolbutamide, ethinylestradiol [e.g., in oral contraceptives]) generally does not have any particular effect.

Terbinafine also does not affect the phenazone or digoxin metabolism.

Terbinafine does not affect the effect of fluconazole (antifungal). Also, no effect has been shown between terbinafine and other drugs taken concomitantly: co - trimoxazole (antimicrobial combination), zidovudine (anti-HIV drug) and theophylline (anti-asthmatic).
Taking Terbiderm concomitantly with some oral anticoagulants (e.g.: warfarin) may cause changes of the coagulation time. The causal relationship is not certain.

In some patients, who have taken terbinafine concomitantly with oral contraceptives, menstrual disturbances have been noticed (e.g. irregular menstruation, bleeding, absence of menstruation). However, these disorders did not occur more frequently than in women who only took oral contraceptives.

Notice that the above information may be valid also for the drugs that have been used recently.

Taking Terbiderm with food and drinks
Terbiderm tablets can be taken before or after food.

Pregnancy and breastfeeding
If you are pregnant or breast - feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.
The clinical experience in pregnant women is very limited. You should not take Terbiderm during pregnancy, unless your doctor considers it necessary.
You should not take Terbiderm tablets if you are breast - feeding.
Terbinafine passes into breast milk and may cause adverse effects to your baby.

Driving and using machines
If you experience dizziness during treatment with Terbiderm, do not drive or operate machinery.

3. HOW TO TAKE TERBIDERM?

Always take Terbiderm exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
<u>The recommended dose is 1 tablet daily.</u>

Method of administration

Taking Terbiderm tablets at the same hour every day, helps you not to forget to take them.
Tablets can be taken before or after food.
Take 1 tablet once daily, with plenty of water.

Duration of treatment

The dosage and duration of treatment are determined by the doctor for each individual.
The instructions below are valid for the mentioned diseases:

Fungal nail infection (subungual onychomycosis)

The duration of treatment is usually 3 months.
If only fingernails are affected, a shorter duration of 6 weeks of treatment may be enough. In the treatment of toenail infection, especially in the big toe nail infection, a longer duration of therapy (≥ 6 months) is indicated in some cases. Slow nail growth (less than 1 mm / month) during the first 12 weeks of treatment is an indication that a prolonged therapy is needed.

In mixed infections, the treatment should be continued only after response to therapy in the first 2 - 3 weeks (growth of healthy nail).

Tinea pedis (interdigital, plantar / moccasin type), tinea corporis and tinea cruris:

The mean duration of treatment is approximately 4 - 6 weeks.

Children

Terbiderm is not recommended for use in children because of limited experience.

Elderly patients

There is no evidence that elderly patients require different dosages or that there are other side effects that are not observed in younger patients.

Please talk to your doctor if you think that the effect of Terbiderm is too strong or too weak.

If you take more Terbiderm than you should

Ask your doctor or hospital for advice immediately. You may need medical treatment. The same thing should be done if someone else has taken this drug by mistake. Initially, your doctor may administer active carbon to remove the drug and if necessary, may take further actions.

The following signs have been noticed from terbinafine overdose: headache, nausea, upper abdominal pain and dizziness.

If you forget to take Terbiderm

Do not take a double dose if you have forgotten to take the previous dose.

Take the tablet as soon as you remember.

However, if there are less than 4 hours left to the regular time to take the next dose, wait and take the next tablet at its usual time.

If you stop taking Terbiderm

The healing process of a mycotic infection requires a long treatment. The complete disappearance of signs and symptoms may take several months because the healthy nail needs time to grow. You can estimate the response to the therapy from the regrowth of the healthy nail. Usually fingernails grow about 2 mm per month and toenails about 1 mm per month. The sick nail grows more gradually. Irregular use or premature interruption of the treatment carries the risk of a new infection. Consult with your doctor if you want to interrupt your treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Some of the side effects may be serious.

In rare cases, Terbiderm may cause liver damage, that in very rare cases may be serious.

Other side effects that may appear include also: decrease of the number of some blood cells, a specific autoimmune disease (lupus erythematosus), severe skin reactions, severe

allergic reactions, inflammation of the blood vessels, inflammation of pancreas or loss of muscle mass.

For the evaluation of side effects, the following frequency indicators are used:

Very common	May affect more than 1 in 10 patients
Common	May affect up to 1 in 10 patients
Uncommon	May affect up to 1 in 100 patients
Rare	May affect up to 1 in 1,000 patients
Very rare	May affect up to 1 in 10,000 patients
Not known	Frequency cannot be estimated from the available data.

Possible side effects

If any of the following side effects appears to you, discontinue the treatment with Terbiderm and if you can, contact your doctor immediately.

Blood and lymphatic system disorders

Uncommon: unusual tiredness or weakness, or difficulty breathing during physical activity [possible signs of the decrease of red blood cells number (anemia)].

Very rare: sporadic cases of drastic decrease of white blood cells (neutropenia, agranulocytosis), platelets (thrombocytopenia) or all the blood cells (pancytopenia) have been reported.

Immune system disorders

Very rare: severe hypersensitivity reactions (anaphylactoid reactions, including angioedema) and appearance or worsening of a specific autoimmune disease (cutaneous or systemic lupus erythematosus).

Not known: severe allergic reactions or infections.

Metabolism and nutrition disorders

Very common: loss of appetite.

Psychiatric disorders

Common: mood disorders (depression).

Uncommon: anxiety (with symptoms such as: sleep disorders, limited ability to think or to concentrate).
Not known: depressive symptoms (e.g. bad mood) secondary to taste disorders.

Nervous system disorders
Very common: headache.
Common: taste disorders or loss of taste, which is usually reversible within 15 weeks after Terbiderm discontinuation. Taste disorders or its loss may last longer in individual cases (up to two years). In very rare cases, the taste disorders have led to loss of appetite, which then has caused an unwanted weight loss due to the reduced food intake.
Uncommon: paresthesia or tingling sensation, reduced sense of touch.
Not known: disorders of the sense of smell, lack of sense of smell for a long time.

Eye disorders
Not known: visual impairment, decreased visual acuity, blurred vision.

Ear and labyrinth disorders
Uncommon: tinnitus (noise or ringing in the ears).
Very rare: vertigo.
Not known: decreased hearing, hearing impairment.

Vascular disorders
Not known: inflammation of the blood vessels.

Gastrointestinal disorders
Very common: abdominal distension, loss of appetite, dyspepsia, nausea, abdominal pain, diarrhea.
Rare: Feeling unwell.
Not known: inflammation of the pancreas.

Hepatobiliary disorders
Rare: liver failure, inflammation of the liver (hepatitis), yellowing of the eyes or skin (jaundice), blocked bile flow (cholestasis), abnormal results of the liver function tests (see section 2).

Very rare: liver failure with subsequent liver transplant or death. In the majority of these cases the patients had serious underlying diseases.

Skin and subcutaneous tissue disorders

Very common: allergic skin reactions (rash associated with itching, urticaria).

Uncommon: increased sensitivity to sunlight, abnormal paleness of the skin, mucous membranes or nail bed (signs of a possible anemia).

Very rare: psoriatic rash or worsening of psoriasis, alopecia (hair loss), rash associated with dandruff or skin peeling. Severe skin reactions associated with blisters or skin peeling (e.g. erythema exudative multiforme [EEM], Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematic pustulosis [AGEP]).

Not known: rash associated with an increase number of some blood cells (eosinophilia) (DRESS).

Musculo-skeletal and connective tissue disorders

Very common: joint pain and muscle pain (arthralgia, myalgia).

Not known: loss of muscular mass.

General disorders and administration site conditions

Common: fatigue.

Uncommon: fever.

Not known: flu-like illness (e.g. tiredness, fever, sore throat, joint pain or muscle pain).

Investigations

Uncommon: weight loss due to taste disorders.

Not known: increased blood levels of a muscle enzyme (creatine phosphokinase).

Measures to be taken

Inform your doctor immediately:

- if you experience symptoms such as: unexplained prolonged nausea, gastrointestinal disorders, loss of appetite, tiredness or unusual weakness, or yellowing of the skin or whites of the eyes (jaundice), dark urine or pale stools unlike the usual (signs of a possible liver disorder); if these symptoms appear, Terbiderm should be discontinued; you should immediately check the liver function;

- if you have fever, chills, sore throat or aphtes due to an infection and weakness or if you suffer from frequent infections;
- if you have unusual bleeding or bruising (possible signs of diseases that affect the blood cells);
- abnormal paleness of the skin, mucous membranes or nail bed, unusual tiredness, weakness or difficulty breathing during physical activity (possible signs of a disease that affects the red blood cells);
- if you have difficulty breathing, dizziness, swelling, mainly in the face and neck, flushes, abdominal spasms with pain and loss of consciousness or joint pain, rigidity, rash, fever or swollen / enlarged lymph nodes (potential signs of a severe allergic reaction);
- if you have symptoms such as: rash, fever, itching, tiredness or if you notice the appearance of small red - purple spots under the skin surface (possible signs of blood vessels inflammation);
- if you have skin problems such as: rash, redness, blisters in lips, eyes or mouth, skin peeling, fever;
- if you have severe upper abdominal pain, which spreads on the back (possible signs of pancreatic inflammation);
- if you have unexplained muscle weakness and pain or dark urine (red - brown) (possible signs of muscle destruction).

Talk to your doctor or pharmacist if you get any side effects or if you notice side effects not listed in this leaflet.

5. HOW TO STORE TERBIDERM?

Keep out of the reach and sight of children!

Keep the blister in the box to protect the content from light.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the package.

6. FURTHER INFORMATION

What Terbiderm contains

The active substance is terbinafine hydrochloride.

1 tablet contains 281.3 mg of terbinafine hydrochloride (equivalent to 250 mg terbinafine).

The excipients are: microcrystalline cellulose, croscarmellose sodium, hypromellose, colloidal anhydrous silica, magnesium stearate, macrogol.

Content of the pack

Box with 30 tablets.

Marketing authorization holder and manufacturer

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