PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Terbina Teva

Tablets

Composition

Each tablet contains:

Terbinafine (as hydrochloride) 250 mg

For information about inactive ingredients see section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of fungal infections of the skin and nails.

Therapeutic class

An oral antifungal agent.

Terbina Teva tablets are used for the treatment of fungal infections of the fingernails and toenails, fungal infection of the hair and scalp (tinea capitis), of the groin and other areas of the body and of the feet (athlete's foot), as well as yeast infections of the skin.

When taken orally, terbinafine reaches the location of infection in sufficiently strong concentrations to eradicate the fungus or halt its growth.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You have or have had a liver disease.
- You are breastfeeding.

Special warnings regarding the use of the medicine

Before treatment with Terbina Teva, you should check whether the following conditions apply to you. If they do, inform the doctor or pharmacist, as Terbina Teva may not be the right medicine for you:

- You are pregnant or trying to become pregnant.
- You have any kidney or liver function problems.
- You have psoriasis.
- You have lupus.
- You have a rash due to high level of white blood cells.

Children and adolescents

This medicine is usually not intended for children.

Tests and follow-up

Blood tests should be performed before and during treatment with Terbina Teva to monitor your liver function.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Rifampicin, for treatment of bacterial infections
- Cimetidine, for treatment of digestive system problems such as an ulcer
- Antidepressants, including tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRI) or monoamine oxidase inhibitors (MAOI)
- Oral contraceptives (may cause irregular menstrual periods and bleeding between periods in some patients)
- Beta blockers or antiarrhythmic agents, for treatment of heart problems
- Warfarin, a blood thinner
- Medicines for treatment of heart problems (such as: propafenone, amiodarone)
- Cyclosporine, which is given following transplantation
- Other medicines for treatment of fungal infections (such as: fluconazole, ketoconazole)
- Cough medicines (such as: dextromethorphan)
- Caffeine

Pregnancy and breastfeeding

Pregnancy

If you are pregnant or planning to become pregnant, consult a doctor before using the medicine.

Breastfeeding

Do not use the medicine while breastfeeding.

Driving and operating machinery

Some patients have reported dizziness while using terbinafine. If you feel dizzy, do not drive or operate machinery.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is: One 250 mg tablet a day.

Do not exceed the recommended dose.

When should Terbina Teva be taken?

Taking the medicine at the same time every day will help you remember when to take it. The tablets may be taken on an empty stomach or after a meal.

Duration of treatment

The duration of treatment depends on the type of infection, its severity and the affected body part. The doctor will tell you for exactly how long you should use the medicine.

The standard duration of treatment is:

For fungal infection of the feet (athlete's foot): The medicine is usually taken for 2-6 weeks.

For fungal and yeast infections of the groin and other areas of the body: The medicine is usually taken for 2-4 weeks.

It is important to take the tablet or tablets every day, and continue the treatment for the duration prescribed by the doctor. This will ensure that the infection will resolve completely and reduce the odds of it returning after you stop taking the tablets.

Hair and scalp infections: The standard duration of treatment is 4 weeks.

Nail infections: Fungal infections of the nails usually take longer to resolve than fungal infections of the skin. For most nail infections, Terbina Teva tablets should be taken for 6-12 weeks.

For fingernail infections: A treatment duration of 6 weeks is sufficient in most cases.

For toenail infections: A treatment duration of 12 weeks is sufficient in most cases.

Certain patients with slow nail growth may require a longer duration of treatment. The doctor will discuss this with you.

How to take the medicine

Do not chew! Swallow the tablets with water.

Terbina Teva tablets can be halved into two equal halves (each half is equivalent to 125 mg).

The tablets should not be crushed due to their bitter taste.

If you accidentally took a higher dosage

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the emergency room of the hospital and take the package of the medicine with you.

Follow the treatment as recommended by the doctor.

If you forgot to take the medicine

If you missed a dose of Terbina Teva, take a tablet as soon as you remember. Take the next dose at the scheduled time, and then continue as usual until you finish the entire treatment. It is important to finish the entire treatment according to the doctor's instructions, unless the doctor has instructed you to stop the treatment.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Terbina Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Severe side effects

Stop taking the medicine and inform the doctor immediately if you notice any of the following rare symptoms:

- Yellowing of the skin or of the eyes. Urine that is darker than usual or light-colored stool, prolonged and unexplained nausea, stomach problems, decreased appetite, unusual tiredness or weakness (possible sign of liver problems), increase in liver enzymes which is observed in blood test results.
- Severe skin reactions, including rash, sensitivity to light, blisters or bruises.
- Weakness, abnormal bleeding, hematomas, abnormal pallor of the skin, abnormal tiredness or weakness or shortness of breath on exertion or frequent infections (possible signs of blood problems).
- Breathing difficulties, dizziness, swelling, mostly of the face and throat, flushing, stomach spasms, 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 purplish spots under your skin (possible signs of blood vessel inflammation).
- Severe abdominal pain radiating to the back (possible sign of inflammation of the pancreas).
- Unexplained muscle pain or weakness or dark (red-brown) urine (possible signs of muscle breakdown).

Additional side effects:

Very common side effects (side effects that occur in more than one out of ten users):

- Headache
- Gastrointestinal problems such as loss of appetite, pain, digestive difficulties, bloated feeling or nausea
- Diarrhea
- Itch, rash or swelling
- Muscle and joint pain

Uncommon side effects that have been reported (side effects that occur in less than one out of 100 users):

Alteration or loss of the sense of taste. This effect usually resolves within several weeks of discontinuation of the treatment. However, a very small number of people (less than 1 out of 10,000) have reported that the disturbance in the sense of taste lasted longer, and as a result they were eating less and losing weight. Moreover, there are reports of some patients who have experienced anxiety or symptoms of depression as a result of this side effect.

Rare side effects (side effects that occur in less than one out of 1,000 users):

- The patient feels unwell, dizziness
- Numbness or tingling

Very rare side effects (side effects that occur in less than one out of 10,000 users):

- Tiredness
- A decrease in the number of certain blood cells. You may notice that bleeding or bruises develop more easily than usual, or you may get infectious diseases more easily and they may be more severe than usual.
- Eruption of a psoriasis-like skin condition, or worsening of psoriasis including rash or eruption of small, pus-filled blisters
- Vertigo
- Hair loss
- Eruption or worsening of lupus (a chronic disease whose symptoms include skin rash and muscle and joint pain)

The following have also been reported: symptoms of blood system disturbances: weakness, abnormal bleeding, bruising or frequent infections. Potentially irreversible disturbances in the sense of smell, impaired hearing, beeping and/or ringing in the ears, flu-like symptoms, elevation in blood levels of a muscle enzyme called creatine phosphokinase (can be detected in a blood test), vision impairment or blurred vision.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **This medicine should be kept in a dark and dry place, below 30°C.**
- Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, Croscarmellose sodium, hydroxypropyl methylcellulose, magnesium stearate, silica colloidal anhydrous.

What does the medicine look like and what are the contents of the package?

Round, flat, white tablets, with a score line on both sides of the tablet. One side of the tablet is debossed with the mark "T" above the score line and with the mark "1" below the score line.

The tablets are packed in blisters. Each package contains: 14, 28, 42, 56, 98 tablets.

Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

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Registration number of the medicine in the national drug registry of the Ministry of Health: **179.08.37559**.

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