PACKAGE LEAFLET: INFORMATION FOR THE USER

Terbinafine/Target®
125 & 250 mg tablets Terbinafine hydrochloride

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Terbinafine/Target® tablets of 125 mg, tablets of 250 mg

1.2. Composition

Active substance: Terbinafien hydrochloride.
Excipients: Cellulose microcrystalline, Sodium starch glycolate, Hypromellose, Silicon dioxide colloidal, Magnesium stearate.

1.3. Pharmaceutical form

Tablets.

1.4. Quantitative composition

Tablets 250 mg: Each tablet contains 250 mg terbinafine.
Tablets 125 mg: Each tablet contains 125 mg terbinafine.

1.5. Description - Packaging

White tablets that can be divided to equal doses, packed in PVC blister/aluminium foil, where product name and characteristics are printed along with the lot number and the expiration date.
Each carton contains 14 or 28 tablets and a leaflet.

1.6. Pharmacotherapeutic group

Antifungal.

1.7. Marketing Authorization Holder

TARGET PHARMA LTD, 54, Menandrou str., 10431, Athens GREECE.
Tel.: +302105224830, Fax: +302105224838,
e-mail: info@targetpharma.gr, http://www.targetpharma.gr

1.8. Manufacturer

KLEVA S.A., Greece.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General information

Terbinafine/Target® is indicated for the treatment of fungal infections of the skin, scalp and nails.

2.2. Indication

Terbinafine/Target® is indicated in adults and children over 12 years of age, for the treatment of tineal skin infections, tinea capitis, tinea corporis, tinea cruris and tinea peris, caused by dermatophytes when oral therapy is considered appropriate due to the site, severity or extent of the infection. Diagnosis should be confirmed via direct microscopic examination of the scraped deseased tissue or culture.
Onychomycosis caused by dermatophytes.
Note:

- Unlike **Terbinafine/Target® cream, Terbinafine/Target® tablets** are not indicated for the treatment of Pityriasis versicolor.
- **Terbinafine/Target®** is indicated for children older than 2 years of age, only for the treatment of scalp desmatophyte infection and when the administration of topical treatment is not possible.

2.3. Contraindications

Hypersensitivity to terbinafine or to any of the excipients.

2.4. Special warnings and precautions for use

2.4.1. General

Terbinafine/Target® tablets are not recommended for patients with chronic or active liver disease. Before prescribing **Terbinafine/Target®** tablets, any pre-existing liver disease should be assessed. Hepatotoxicity may occur in patients with and without pre-existing liver disease. Patients prescribed **Terbinafine/Target®** tablets should be instructed to report immediately any signs or symptoms of unexplained persistent nausea, anorexia, tiredness, vomiting, right upper abdominal pain or jaundice, dark urine, or pale stools. Patients with these symptoms should discontinue taking oral terbinafine and the patient's liver function should be immediately evaluated.

In patients with renal impairment (creatinine clearance ≤ 50 ml/min or serum creatinine of more than 300 μmol/L) should receive half the regular dose.

2.4.2. Elderly

There are no evidence that the elderly patients require different dosages or present different side effects than other patients. In this age group the possibility of past impairment in the liver or kidney function should be considered.

2.4.3. Pregnancy

Terbinafine/Target® should not be used during pregnancy, unless the expected benefits of the treatment overcome the possible risks.

2.4.4. Lactation

Terbinafine can be detected to the breast milk, so women treated with **Terbinafine/Target®** tablets should not breast feed.

2.4.5. Children

Children under 12 years of age: Safety and efficacy has not been established in this age group except for the indication “treatment of dermatophyte infection of the scalp”.

- Children older than 2 years of age only for the treatment of dermatophyte infection of the scalp and only if the topical treatment is not possible.

- There are no available data for children younger than 2 years of age (usually <12 kg) for the "treatment of dermatophyte infection of the scalp".

2.4.6. Effects on the ability to drive and use machines

There are no available data on the effects of **Terbinafine/Target®** to the ability to drive or use machines.

2.5. Interactions with other medicines or substances

Before you take **Terbinafine/Target® tablets** you should tell your doctor if you are taking any other medication including contraceptives and any other medicine that you get without prescription from a pharmacy. You should also inform your doctor for medicines that you take and:

- metabolized in CYP2D6, e.g. medicines that belong to the therapeutic categories of tricyclic antidepressants, b-blockers, selective serotonine reuptake inhibitors (SSRIs), class 1C antiarrhythmics and Monoaminoxidase inhibitors type B.
- Metabolised in cytochrome P450 (such as terfedine, triazolam, cyclosporine, tolbutamide, oral contraceptives)
- Affect cytochrome P450 function (such as rifampicin, cimetidine)
- If you receive via IV caffeine or desipramine.

2.6. Posology

Take this medicine exactly as your has prescribed for you.

Children

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

- Children older than 12 years of age: 250 mg once daily.
- Children younger than 12 years of age: safety and efficacy has not been established in this age group except for the indication "treatment of dermatophyte infection of the scalp".
- Children older than 12 years of age: only for the "treatment of dermatophyte infection of the scalp" and if the topical treatment is not possible.:

- Children weighing less than 20 kg: 62,5 mg (half tablet of 125 mg) once daily.
- Children weighing between 20 kg to 40 kg: 125 mg (one tablet of 125 mg or half tablet of 250 mg) once daily.
- Children weighing over 40 kg: 250 mg (2 tablets of 125 mg or one tablet of 250 mg) once daily.

- There are no data available for children younger than 2 years of age (usually <12 kg) for the "treatment of dermatophyte infection of the scalp".

Adults

250 mg once daily or 125 mg twice a day.
The duration of the treatment varies according to the indication and the severity of the infection:

Skin infections (dermatophyte)

The duration of the treatment recommended is as follows:

- Tinea pedis (interdigital, plantar and moccasin type): 2-6 weeks.
- Ttinea corporis: 2-4 weeks.
- Tinea cruris: 2-4 weeks.

Total remission of signs and symptoms of the infection may not occur until after several weeks of treatment.

Fungal infections of the scalp

- Tinea capitis: 4 weeks.

Onychomycosis
A 6 week treatment is usually sufficient for the fingernail onychomycosis. For the respective infection in toenails a treatment of 3 months is recommended. Exception is for the infection that affects the big toes, where the duration of the treatment may exceed 6 months. Slower nail growth, especially during the early treatment, may indicate that the duration of the treatment with **Terbinafine/Target®** should be longer. For the younger patients for whom the nail growth is faster the duration of the treatment may be shorter.
The optimal clinical effect will appear in a few months, when the nails will no longer host fungus, all symptoms of the infection have been remised and healthy nails are fully developed.

2.7. Overdose - Management

A few cases of overdose (up to 5g) have been reported, where the symptoms were headache, nausea, epigastric pain and dizziness.
Management of overdose: Administration of activated charcoal to eliminate the excess drug, followed by symptomatic supportive treatment as needed.
Poison Center Athens: +30 210 7793777.

2.8. What should the patient know if fails to take a dose

If you miss a dose, take it as soon as you remember, unless it is almost time for your next dose, within the next 4 hours. In this case, continue taking the usual dose of **Terbinafine/Target®** once daily, as recommended.

2.9. Possible side effects

Terbinafine/Target® tablets are well tolerated in general. Side effects are mild to moderate and usually transient.
The following adverse reactions have been reported in clinical studies or during the post marketing experience.
Side effects are categorized according to the occurrence frequency under the following terms: Very common (≥1/10), Common (≥1/100, <1/10), Uncommon (≥1/1.000, <1/100), Rare (≥1/10.000, <1/1.000), Very uncommon (<1/10.000), including any isolated reports.

General disorders	
Very Rare	Anaphylactic reactions including angioedema.
Blood and lymphatic system disorders	
Very rare	Neutropenia, agranulocytosis, thrombocytopenia.
Immune system disorders	
Very rare	Manifestation or aggravation of cutaneous or systemic lupus erythematosus.
Nervous system and psychiatric disorders	
Uncommon	Taste disturbances, including taste loss, which is reversible after discontinuation of the drug. There are rare reports of prolonged taste disturbances. In few isolated cases was reported that the taste loss led to decreased food intake and significant weight loss.
Rare	Headache, poor concentration, fatigue
Hepato bilary disorders	
Rare	Hepatobilary dysfunction (cholestatic type mainly) has been observed

	during treatment with Terbinafine, including cases of severe liver failure (outcome death or liver transplantation). In such cases patients were suffering from underlying systemic conditions and the causality for terbinafine is uncertain.
Gastrointestinal disorders	
Very common	Symptoms like fullness sensation, loss of appetite, dyspepsia, nausea, mild abdominal pain, diarrhea.
Skin and subcutaneous tissue disorders	
Very common	Mild skin reactions (rash, urticaria).
Very Rare	Severe skin reactions (e.g. Stevens-Johnson syndrome, toxic epidermal necrosis). If the skin rash worsens during treatment with Terbinafine the treatment should be discontinued. Hair loss, although the causality of Terbinafine has not been confirmed.
Musculoskeletal and connective tissue disorders	
Very common	Musculoskeletal reaction such as arthralgia, myalgia)

Συμβουλευτείτε το γιατρό σας αν παρατηρήσετε ότι κάποια από αυτές τις ανεπιθύμητες ενέργειες είναι έντονη ή επίμονη. Ειδοποιήστε το γιατρό σας αμέσως αν παρατηρήσετε εξελισσόμενο κοκκίνισμα στο δέρμα, τύπου ιλαράς, γιατί η θεραπεία πρέπει να διακοπεί. Αν τυχόν παρουσιάσετε ηπατίτιδα ή βλάβη της χολής ή του ήπατος, πρέπει να διακόψετε τη θεραπεία με **Terbinafine/Target®** δισκία.

2.10. What should the patient know about the expiration date

Indicated in inner and outer packaging.
Do not use after the expiry date.

2.11. Special warnings about the storage of the product

Store tablets in the original package to protect from direct light. Keep out of reach and sight of children.

2.12. Date of last revision of the text

2 Νοεμβρίου 2007.

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.

- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

This product is subjected to medicinal prescription.