

PACKAGE LEAFLET: INFORMATION FOR THE USER

Terbinafine/Target®
1% cream
1% cutaneous spray solution
Terbinafine hydrochloride

1. IDENTIFICATION OF THE MEDICINAL PRODUCT**1.1 Trade name**

Terbinafine/Target® cream.

Terbinafine/Target® cutaneous spray solution.

1.2 Composition

Active substance: Terbinafine hydrochloride.

- a) Cream Excipients: Isopropyl myristate, Polysorbate 60, Cetyl alcohol, Cetyl palmitate, Stearyl alcohol, Sorbitan stearate, Benzyl alcohol, Sodium hydroxide, Water purified.
- b) Cut.sp.sol. Excipients: Ethanol 96%, Propylene glycol, Cetomacrogol 1000, Water purified.

1.3 Pharmaceutical form

a) **Terbinafine/Target®** cream for topical external use.

b) **Terbinafine/Target®** cutaneous spray solution for external use.

1.4 Quantitative composition

a) Each gram of cream contains 10 mg Terbinafine hydrochloride.

b) Each gram of cutaneous spray solution contains 10 mg Terbinafine hydrochloride.

1.5 Nature and content of container

a) Each carton contains:

- Tube of 15 g of white cream, with slight odor and a leaflet.
- Tube of 30 g of white cream, with slight odor and a leaflet.

b) Each carton contains:

- White bottle of 15 ml cutaneous solution, with crimped mouth and spray pump and a leaflet.
- White bottle of 30 ml cutaneous solution, with crimped mouth and spray pump and a leaflet.

1.6 Pharmacotherapeutic group

Antifungal (ATC: D01AE15).

1.7 Marketing Authorization Holder

TARGET PHARMA, 54 Menandrou, 104 31 Athens Greece,

Tel: +30 210 5224830, Fax: +30 210 5224838,

E-mail: info@targetpharma.gr, <http://www.targetpharma.gr>

1.8 Manufacturer

Pharmaceutical Industry PROEL S.A, Greece.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1 General information

The active ingredient of the medicine, terbinafine, is used to treat fungal infections of the skin, scalp and nails of adults.

2.2 Indications

Terbinafine/Target[®] is indicated for the treatment of skin fungal infections, caused by dermatophytes such as Tricophytes (e.g. *T. rubrum*, *T. mentagrophytes*, *T. verrucosum*, *T. violaceum*), *Microsporum canis* and *Epidermophyton floccosum*.

a) **Terbinafine/Target[®]** cream is indicated for the treatment of:

- Tinea skin infections (*Tinea corporis*, *T. cruris*)
- Foot dermatomycosis (*Tinea pedis*)
- Skin moniliasis (candidiasis) caused by yeasts of *Candidasp.* (e.g. *Candida albicans*)
- Pityriasis versicolor caused by *Pityrosporum orbiculare* (also known as *Malassezia furfur*)

b) **Terbinafine/Target[®]** cutaneous spray solution is indicated for the treatment:

- Tinea skin infections (*Tinea corporis*, *T. cruris*)
- Foot dermatomycosis (Interdigital type and *Tinea pedis*)
- Pityriasis versicolor

2.3 Contraindications

All medicine are administered to help the patients. In some cases issues may arise when the medicines are not taken as instructed.

Before you take **Terbinafine/Target[®]** cream or **Terbinafine/Target[®]** cutaneous spray solution you should inform your doctor in the following cases:

1. If you ever had any allergic or any other unusual reaction to this medicine or to any of the excipients of the product.
2. If during treatment you are pregnant or intent to get pregnant (see section 2.4.3 “Pregnancy”).
3. If you are breast-feeding (see section 2.4.4 “Lactation”).

2.4 Special warnings and precautions for use

2.4.1 General

If during treatment experience any side effect (see section 2.8) or if you feel that there is no improvement in your condition or even it is worse, then you stop taking the medicine and inform your doctor.

Keep this medicine out of reach of children.

a) **Terbinafine/Target[®]** cream is only for external use only. Avoid contact with eyes.

b) **Terbinafine/Target[®]** cutaneous spray solution is for external use only. Avoid use in the face. Avoid contact with eyes, or wounds as alcohol contained in the solution may cause irritation. In case of accidental eye contact, rinse thoroughly with excess clean water. In case of accidental inhalation consult your doctor for any symptom develop or persist.

2.4.2 Elderly

There is no evidence suggesting that elderly patient require alterations in dosage or experience side effects other than those of younger patients.

2.4.3 Pregnancy

- a) There is no clinical experience with **Terbinafine/Target[®]** cream in pregnant women.
- b) Since there is very limited clinical experience with the use of **Terbinafine/Target[®]** cutaneous spray solution in pregnant women, it should only be used if it is absolutely needed during pregnancy. Your prescribing doctor will evaluate if the expected benefit outweigh the possible risk and pregnant women should not use this medicine without medical supervision.

2.4.4 Lactation

Terbinafine is excreted in breast milk therefore, women during breast-feeding should not use **Terbinafine/Target[®]** cream or **Terbinafine/Target[®]** cutaneous spray solution.

Additionally, infants should not get in contact with skin treated with these medicines including breast skin.

2.4.5 Children

There is limited experience in the used of **Terbinafine/Target[®]** in children. Therefore, this treatment is not recommended.

2.4.6 Effects on driving and using machines

None.

2.4.7 Special warnings about excipients

Terbinafine/Target[®] cutaneous spray solution contains alcohol and may cause irritation if applied on wounds.

2.5 Interactions with other medicines or other forms of interaction

None.

2.6 Posology

Relief of clinical symptoms usually occurs within few days. Irregular use or premature discontinuation contains the risk of recurrence.

Deep clean and thoroughly dry the infected skin before the application of **Terbinafine/Target[®]**.

- a) **Terbinafine/Target[®]** cream can be applied once or twice daily.

The duration of the treatment is as follows

- Tinea corporis, Tinea cruris: 1 week
- Tinea pedis: 1 week
- Cutaneous candidiasis: 1 week
- Pityriasis versicolor: 2 weeks

Apply a thin layer of the cream on the infected skin and the surrounding area and massage gently. If the affected area is in contact with other parts of the body, the treated area may be covered with gauze, especially during the night.

b) **Terbinafine/Target**[®] cutaneous spray solution is applied once or twice daily, depending on the indication.

Before you use **Terbinafine/Target**[®] cutaneous spray solution for the first time, depress the actuator up to 3 times for the proper dispensing of the solution. A sufficient amount of solution should be applied in the infected and surrounding area.

The frequency of treatment may vary depending on the type and severity of the infection, but the duration cannot exceed one week as follows:

- Tinea corporis, Tinea cruris: once daily for 1 week
- Interdigital type Tinea pedis: once daily, for 1 week
- Pityriasis versicolor: twice daily for 1 week

Administration of **Terbinafine/Target**[®] cutaneous spray solution should be in accordance to the above instructions.

If during the treatment you feel that your conditions is not improved or even if it is worse, stop the treatment and consult your doctor.

2.7 Overdose - Management

No case of overdose has been reported with **Terbinafine/Target**[®] cream or cutaneous spray solution. In the accidental case that a patient shallow cream or cutaneous solution of terbinafine, the possible side effects expected are the same as with **Terbinafine/Target**[®] tablets (nausea, headache or abdominal pain and vertigo). Alcohol content (23.5%) should be considered in **Terbinafine/Target**[®] cutaneous spray solution. In case of accidental ingestion, contact your doctor immediately and go to the nearest hospital to seek treatment.

Poison Center Athens, Tel: +30 210 7793777

2.8 Possible side effects

Like all medicine **Terbinafine/Target**[®] cream or cutaneous spray solution may cause side effects.

In case you experience in the treated area rush, numbness, itching or any other side effect contact you doctor or pharmacist.

It is rarely needed to stop the treatment due to side effects. You should be ready to answer your doctor to help him understand if your symptoms are harmless or if you have severe allergic reactions such as urticaria, rush, wheals or bullae lesion which are very rare you stop the treatment and seek medical help.

If you get any side effects, please talk to your doctor or pharmacist or any other health care provider or directly to the National Medicines Agency (284 Mesogion Av., 15562, Chologos, Athens, Greece www.eof.gr).

2.9 What you should know in case you forget to take one dose

If you forget to use **Terbinafine/Target**[®], apply the medicine as soon as you remember. If it is about the time for your next dosage do not use the forgotten dosage, continue your treatment as planned.

Do not double dosages.

2.10 Expiration date

Expiration date is mentioned in outer and immediate container. Do not use after the expiration date.

2.11 Special warnings about the storage of the product

Terbinafine/Target[®] cream and **Terbinafine/Target[®]** cutaneous spray solution should not be stored at temperature above 25°C. Keep out of reach of children. Do not refrigerate.

2.12 Date of last revision of this leaflet

14-12-2012

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

- a) **Terbinafine/Target[®]** cream: subjected to medicinal prescription.
- b) **Terbinafine/Target[®]** cutaneous spray solution: not subjected to medicinal prescription.