



**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

**TERBINAFINE HYDROCHLORIDE CREAM  
1%W/W  
TAJ PHARMA**

Terbinafine

**Read all of this leaflet carefully before you start taking this medicine because it contains 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

**WHAT IS IN THIS LEAFLET**

1. What Terbinafine Cream is and what it is used for
2. What you need to know before you take Terbinafine Cream
3. How to use Terbinafine Cream
4. Possible side effects
5. How to store Terbinafine Cream
6. Contents of the pack and other information

**1. WHAT TERBINAFINE CREAM IS AND WHAT IT IS USED FOR**

Terbinafine Cream is used to treat patients with fungal and certain yeast infections of the skin. It attacks and kills the fungus or yeast which is causing your infection.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE**

**Do NOT use Terbinafine Cream if you:**

- are allergic (hypersensitive) to any of the ingredients in the product (see Section 6)
- The cream is NOT recommended for use on children.

**Take special care with Terbinafine Cream**

The cream is for external use only. Do not use on the face. Avoid contact with eyes. In case of accidental contact with eyes, rinse thoroughly with running water.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

**Pregnancy and breast-feeding**

Do not use the cream if you are pregnant or breastfeeding, unless advised to by your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Terbinafine Cream is not expected to affect your ability to drive or operate machinery.

**Important information about some of the ingredients of Terbinafine Cream**

- cetyl alcohol and stearyl alcohol: May cause local skin reactions (e.g. contact dermatitis). For other ingredients see Section 6.

**3. HOW TO USE TERBINAFINE CREAM**

**Adults**

Your doctor will decide the right amount of Terbinafine Cream for you to use and will tell you for how long to use your medication. Apply the cream once or twice a day, for one to two weeks, but this will depend upon the type and area of infection. Infections usually appear to improve within a few days of starting to use Terbinafine Cream, but may reappear if the cream is not applied regularly or is stopped too early.

**Directions for use:**

- Cleanse and dry the affected areas thoroughly and wash your hands. Treatment can be helped by keeping the affected areas clean by regular washing and careful drying with your own clean towels and clothes, and not rubbing or scratching the skin.
- Unscrew the cap then gently squeeze out a small amount of the cream onto your finger.
- Apply just enough cream to form a thin layer on the affected skin and surrounding areas.
- Rub in gently. When used between the toes,



buttocks or on the groin, the treated area may be covered with a light, fresh gauze strip, especially at night.

- Replace the cap on the tube and wash your hands.

Even though you will not be using Terbinafine Cream during the second week for athlete's foot, full skin healing after the infection has cleared will continue for up to 4 weeks. If you have not noticed any signs of improvement within 2 weeks of first starting treatment, please seek advice from your doctor or pharmacist.

#### **Children**

Use in children is NOT recommended, since there are no data to support use in this population.

#### **If you accidentally swallow Terbinafine Cream**

Contact your doctor or nearest hospital emergency department if you, or someone else, has swallowed some cream. Take any remaining medicine and this leaflet with you if possible. Symptoms of accidental ingestion include headache, nausea (feeling sick), dizziness and stomach pain.

#### **If you forget to use Terbinafine Cream**

If you miss an application, apply the cream as soon as possible then continue your treatment as before. If you only remember at the time of your next application, just apply the cream and carry on as normal. It is important to try to use the cream at the correct times as forgotten applications could risk the infection returning.

#### **If you stop using Terbinafine Cream**

Infections may come back if you do not use the cream regularly, or if you stop the treatment too early. If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECT**

Like all medicines, Terbinafine Cream can cause side effects, although not everybody gets them. **STOP using** the cream and seek **medical help immediately** if you have any of the following very rare **allergic reactions**:

- difficulty breathing or swallowing, swelling of the mouth, face, lips, tongue or throat (severe allergic reaction).
- severe itching of the skin, with a red rash or raised lumps, hives or blisters.

**Common:** (may affect up to 1 in 10 people): skin peeling, itching.

**Uncommon:** (may affect up to 1 in 100 people): skin lesions, scab, skin colour changes, redness, burning, pain and irritation at the site of application. These common and uncommon side effects are usually harmless and you can carry on using the cream.

**Rare:** (may affect up to 1 in 1000 people): eye irritation, dry skin, contact dermatitis, eczema, worsening of symptoms.

**If any of these side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor.**

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. HOW TO STORE TERBINAFINE CREAM**

Keep out of the sight and reach of children. Keep the tube closed and in the carton. Do not use this medicine after the expiry (EXP) date shown on the box and tube. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. CONTENTS OF THE PACK AND FURTHER INFORMATION**

##### **What Terbinafine Cream contain**

Each gram of cream contains:  
Terbinafine hydrochloride equivalent to 8.89 mg of Terbinafine.....10mg  
Excipients.....q.s.

The other ingredients are sodium hydroxide, benzyl alcohol, sorbitan stearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate, purified water.

##### **What Terbinafine Cream look like and contents of the pack**

White The cream is a white cream, available in



aluminium or laminate tubes of 15 g or 30 g. Not all pack sizes may be marketed.

**7. MANUFACTURED IN INDIA BY:**

**TAJ PHARMACEUTICALS LTD.**

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