

**Package leaflet: information for the user****Terbinafine 10mg/g cream****Terbinafine hydrochloride****Read all of this leaflet carefully before you start using 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.

**What is in this leaflet:**

1. What Terbinafine Cream is and what it is used for
2. What you need to know before you use 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 an antifungal medication indicated for the treatment of skin infections caused by dermatophyte fungi (e.g. *Trichophyton*) or yeasts (e.g. *Candida Albicans*) and for the treatment of pityriasis (tinea) versicolor.

**2. What you need to know before you use Terbinafine Cream****Do not use Terbinafine Cream**

- if you are allergic to terbinafine or to any of the other ingredients of this medicine (listed in section 6)

**Warnings and precautions**

Talk to your doctor before using /.../.

Terbinafine Cream is for external use only. Do not allow the cream to come in contact with your eyes, mucosa or lesions. Should the cream accidentally come into contact with one of these areas, rinse with plenty of running water.

**Other medicines and Terbinafine Cream**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not apply other medicinal products on the treated areas.

There are no known interactions of Terbinafine Cream with other medicinal products.

**Pregnancy, breast-feeding and fertility**

Ask your doctor or pharmacist for advice before taking any medicine.

There is no clinical experience with terbinafine in pregnant women.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

Because terbinafine pass into the breast milk, you should not use Terbinafine Cream if you are nursing a child unless specifically prescribed by your doctor. Ask your doctor if you should discontinue nursing while using Terbinafine Cream.

**Driving and using machines**

Application of Terbinafine Cream to the skin does not affect the ability to drive or use machines.

**Terbinafine Cream contains stearyl alcohol and cetyl alcohol**

These compounds may cause local skin reactions (e.g. contact dermatitis).

**3. How to use Terbinafine Cream**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For cutaneous use.

Before applying the cream, the skin must be carefully washed and dried.

Smear a thin layer of cream on the inflamed skin and a little round about. Rub the cream in gently.

If the inflammation is in a skin fold (under the breasts, between the toes or fingers, in the groin or between the buttocks) the skin can be covered with a sterile gauze, especially at night. Wash your hands after rubbing in, unless your hands are the area that is being treated.

**Adults and children from 12 years of age**

Duration and frequency of treatment is once to twice a day for 1 to 2 weeks depending on the infection.

An improvement in the symptoms usually occurs after a few days. Irregular use or premature stoppage of the cream increases the chance of the symptoms recurring. If no improvement has occurred after 1 to 2 weeks, contact your doctor or pharmacist.

**Use in Children**

There is only limited experience with the administration of terbinafine to the skin of children under the age of 12 years and therefore use in this age group is not recommended.

**If you use more Terbinafine Cream than you should**

An overdose is unlikely to occur with application of Terbinafine Cream to the skin. However, in the event that the cream is accidentally ingested, undesirable effects similar to those observed with an overdose of terbinafine in tablet form would be expected. These include headaches, nausea, stomach pain and dizziness.

Should you accidentally ingest more than one 30 g tube of the cream, go to the nearest emergency room.

**If you forget to use Terbinafine Cream**

Continue the treatment as usual.

Do not apply an extra dose to make up for a forgotten dose.

**If you stop using Terbinafine Cream**

Follow the recommended length of treatment. Premature stoppage of using the cream increases the chance of the symptoms recurring. If no improvement has occurred after 1 to 2 weeks, contact your doctor or pharmacist.

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 can cause side effects, although not everybody gets them.

Redness, skin rash , itching or a stinging sensation can occur at the site where the cream is applied.

*Rare side effects* (may affect up to 1 and 1,000 people):

Allergic reactions which could cause e.g. swelling, pain, skin rash or hives and may require treatment to be discontinued.

If you get any side effects, talk to your doctor or pharmacist . This includes any side effects not listed in this leaflet.

**5. How to store Terbinafine Cream**

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Once the tube is opened, the medicinal product should be used within 6 months.

Do not use Terbinafine Cream if you notice signs of deterioration of the cream.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Terbinafine Cream contains**

- One gram of cream contains 10 mg of terbinafine hydrochloride.
- The other ingredients are: Stearyl alcohol, cetyl alcohol, sorbitan stearate, cetyl palmitate, isopropyl myristate, benzyl alcohol, polysorbate 60, sodium hydroxide and purified water.

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

White cream. The cream is supplied in a white collapsible tube with a varnished inner lining sealed with latex, with a sealed closure and perforating cap.

#### *Pack sizes:*

7.5 g tube

15 g tube

30 g tube

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

Actavis Group PTC ehf  
Reykjavíkurvegur 76-78  
220 Hafnarfjörður  
Iceland

### **Manufacturer:**

Pharbil Waltrop GmbH  
Im Wirrigen 25  
D-45731 Waltrop  
Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

[To be completed nationally]

**This leaflet was last approved in**