

PACKAGE LEAFLET

Package leaflet: Information for the user

Terbinafine 1 % 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. See section 4.

In this leaflet:

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

1. What Terbinafine 1% Cream is and what it is used for

Terbinafine 1% Cream contains the active ingredient terbinafine hydrochloride which is an antifungal. It kills fungi, which cause skin infections. Terbinafine 1% cream is used for the local treatment of fungal infections of the skin only.

2. What you need to know before you use Terbinafine 1% Cream

Do not use Terbinafine 1% cream

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

Warnings and precautions

Talk to your doctor or pharmacist before using Terbinafine 1% Cream.

This cream is for external use only.

Avoid contact with the eyes. If the cream gets in your eyes accidentally, rinse thoroughly with running water and tell your doctor immediately.

In the event of allergic reaction, the cream should be removed and the treatment interrupted.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and Terbinafine 1% Cream

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

Pregnancy and breast-feeding

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

If you are pregnant you should not use Terbinafine 1% cream unless it is clearly necessary and advised to by your doctor.

Do not use this cream if you are breast-feeding as terbinafine hydrochloride can pass into breast milk. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Terbinafine 1% cream should not affect your ability to drive or operate machines.

Terbinafine 1% cream contains benzyl alcohol, cetyl alcohol and cetostearyl alcohol

This medicine contains 10 mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation. This medicine also contains cetyl alcohol and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE TERBINAFINE 1% CREAM

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

Adults (including older people)

Terbinafine 1% Cream may be applied 1-2 times daily. The recommended duration and frequency of treatment will depend upon the type and area of infection:

Tinea pedis (Athlete's foot): 1 week.

Tinea cruris (dhotie itch/jock itch) and Tinea corporis: 1-2 weeks.

Cutaneous Candida: 2 weeks.

Pityriasis versicolor: 2 weeks.

Infections usually appear to improve within a few days of starting to use the cream. It is important that you use the cream regularly even if the infection has improved. If you see no improvement in your skin condition after 2 weeks, talk to your doctor.

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 1% 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.

Use in children

Terbinafine 1% Cream is not recommended for children under 12 years.

If you use more Terbinafine 1% Cream than you should

Remove some of the cream if you apply more than a thin layer.

If you or someone else swallows the cream, go to your doctor or nearest hospital emergency department immediately. 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 the cream gets in your eyes, rinse thoroughly with running water and tell your doctor immediately.

If you forget to use Terbinafine 1% cream

If you forget to use the cream, apply it as soon as you remember. If it is time for the next application, carry on as normal. It is important to try to remember to use the cream or you risk the infection returning.

If you stop using Terbinafine 1% cream

Do not stop using Terbinafine 1% cream before the recommended time, as the infection will be more likely to return.

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.

STOP using the cream and seek medical help immediately if you have any of the following very rare allergic reactions:

Not known (cannot be estimated from the available data):

- 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.

Other side effects

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 effects are harmless and usually you can continue with the treatment.

Rare (may affect up to 1 in 1,000 people):

- eye irritation, dry skin, contact dermatitis, eczema, worsening of symptoms.

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Terbinafine 1% Cream

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

Do not use Terbinafine 1% cream after the expiry date stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Store in the original container. Do not freeze. Keep the tube tightly closed.
Discard the tube 28 days after first opening the tube.

Do not throw away any medicine 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 1% cream contains

- The active substance is terbinafine hydrochloride. One gram of cream contains 10 mg of terbinafine hydrochloride equivalent to 8.89 mg of terbinafine.
- The other ingredients are sodium hydroxide, benzyl alcohol, sorbitan monostearate, cetyl palmitate, cetyl alcohol, cetostearyl alcohol (see section 2 “Terbinafine 1% Cream contains cetyl alcohol and cetostearyl alcohol”), polysorbate, isopropyl myristate and purified water.

What Terbinafine 1% cream looks like and the contents of the pack

Terbinafine 1% Cream is a white or almost white cream with a slight almond odour contained in aluminium tubes of, 7.5 g, 15 g or 30 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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This leaflet was last revised in 01/2022