Package leaflet: Information for the patient

Terbza 98 mg/ml cutaneous solution
terbinafine

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.

What is in this leaflet

1. What Terbza is and what it is used for

Terbza contains the active substance terbinafine, which belongs to a group of medicines known as antifungals. It kills a variety of fungi that can cause nail infections.

Terbza is used to treat mild to moderate **fungal infections** of the **fingernails and toenails** in adults.

2. What you need to know before you use Terbza

Do not use Terbza

- 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 Terbza if :
- the part of the nail next to the cuticle is affected
- you have diabetes
- you have a disease affecting the immune system or take any medicines that might affect the immune system
- you have poor circulation, swelling or ulcers, in your legs or feet (peripheral vascular disease)
- you have injured, painful or severely damaged nails
- you have psoriasis that causes red itchy skin and scaly patches or any other chronic skin condition
- you have yellow nails together with oedema and breathing difficulties (yellow nail syndrome)

Terbza is for use only on nails. Avoid contact with eyes and mucous membranes. Rinse thoroughly with running water, in case of any contact with the eyes or mucous membranes.

Children and adolescents

Terbza should not be used by children and adolescents under 18 years of age, due to the lack of experience in this age group.

Other medicines and Terbza

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. It is unlikely that Terbza will influence or be influenced by other medicines you are using as it acts only locally in the nail.

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 using this medicine.

The use of Terbza may be considered during pregnancy and breast-feeding, if the doctor considers it necessary.

Do not allow infants to come into contact with any treated areas. Make sure infants do not suck on your treated nails.

Driving and using machines

Terbza does not affect your ability to drive and use machines.

Terbza contains propylene glycol

This medicine contains 0.7 g propylene glycol in each millilitre solution.

3. How to use Terbza

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

Only for use on fingernails and toenails.

Before application of Terbza, remove any nail polish or other cosmetic product from the nails and adjacent skin.

Dosage

Adults

- Apply a thin layer **once daily** over the entire surface of the **affected nails and under the free nail edge**, using the tip of the tube.
- Do not apply on the surrounding skin.
- Wait about 5 minutes until the solution has completely dried.
- The treated nails should not be washed or get wet for at least 8 hours. Therefore, application in the evening before going to bed and after showering or bathing is recommended.

Do not apply Terbza to the nail bed if the affected nail or parts of the affected nail have detached from the underlying nail bed.

Duration of treatment

Treatment should be continued until each treated nail is clear or its appearance has improved significantly, and new, healthy nail has regrown. In general, the duration of treatment for fingernails is about 6 months while for toenails it is 9 to 12 months. You may experience some degree of improvement after 12 weeks, but it takes longer for the nail to be completely cured.

If you use more Terbza than you should

Due to how this medicine is used, an overdose is highly unlikely. If you, or anyone else, accidentally swallows the solution, contact your doctor or hospital straight away for advice..

If you forget to use

If you miss an application, apply the solution as soon as possible on the same day. Then continue your treatment as before.
Do not use a double dose to make up for a forgotten use.

If you stop using Terbza

Do not stop using Terbza before the infected nails are clear of visible disease, or your doctor or pharmacist recommends.
Fungal nail infections may return if you do not use the solution regularly, or you stop treatment too early.

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.

Side effects can occur with following frequencies:
Common (may affect up to 1 in 10 people)
- whitish or yellowish nail
- detachment of the nail from the nail bed
- separation of part of the nail that may lead to shedding from the free edge of the nail
- inflammation of the nail fold or cuticle with or without bacterial infection
- red itchy rash as a reaction to contact with the medicine
- skin redness

Uncommon (may affect up to 1 in 100 people)
- nail disorders and skin reactions around the treated nails: skin irritation, skin inflammation, itchy skin

Some side effects like for example nail discolouration and nail detachment can also be caused by the fungal infection.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Terbza

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

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

Store below 25°C. Do not freeze.

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 Terbza contains

- The active substance is terbinafine. One millilitre of solution contains terbinafine hydrochloride equivalent to 98 mg terbinafine.

- The other ingredients are propylene glycol (E 1520), urea, lactic acid, disodium edetate (EDTA), sodium hydroxide (for pH-adjustment) and purified water.

What Terbza looks like and contents of the pack

Terbza is a clear, colourless cutaneous solution packed in plastic tubes with a silicone tip applicator and closed with a plastic cap.

Pack sizes: 5 ml, 10 ml
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Moberg Pharma AB
Gustavslundsvägen 42
167 51 Bromma
Sweden

Manufacturer

C.P.M. Contract Pharma GmbH
Fruehlingstrasse 7
83620 Feldkirchen-Westerham
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria: Terbinafin Moberg Pharma 98 mg/ml Lösung zur Anwendung auf der Haut
Belgium: Terbinafine Moberg Pharma 98 mg/ml solution pour application cutanée / Terbinafine Moberg Pharma 98 mg/ml solution oplossing voor cutaan gebruik / Terbinafine Moberg Pharma 98 mg/ml solution Lösung zur Anwendung auf der Haut
Czech Republic: Terbinafin Moberg Pharma 98 mg/ml kožní roztok
Denmark: Terbinafin Moberg Pharma 98 mg/ml Kutanopløsning
Finland: Terbinafin Moberg Pharma 98 mg/ml liuos iholle
France: Terbinafine Moberg Pharma 98 mg/ml solution pour application cutanée
Hungary: Terbinafin Moberg Pharma 98 mg/ml külsőleges oldat
Ireland: Terbza 98 mg/ml cutaneous solution
Italy: Terbinafina Moberg Pharma 98 mg/ml soluzione cutanea
Netherlands: Terbinafine Moberg Pharma 98 mg/ml oplossing voor cutaan gebruik

Norway: Terbinafin Moberg Pharma 98 mg/ml liniment, oppløsning
Spain: Terbinafina Moberg Pharma 98 mg/ml solución cutánea
Sweden: Terbinafin Moberg Pharma 98 mg/ml kutan lösning

This leaflet was last revised in 2023-06-28