

Package leaflet: Information for the patient

Terclara 98 mg/mL cutaneous solution terbinafine

[For medicines available only on prescription:]

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.

[For medicines available without a prescription:]

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if your symptoms do not improve or get worse after 6 months for fingernails and 9 to 12 months for toenails.

What is in this leaflet

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

1. What Terclara is and what it is used for

Terclara 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.

[For medicines available only on prescription:]

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

[For medicines available without a prescription:]

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

[SE OTC addition:] Terclara can be used when you have previously been diagnosed by a doctor and the infection does not involve the nail growth zone. You may also need to start a new treatment if the infection recovers.

[To be completed nationally]

2. What you need to know before you use Terclara

Do not use Terclara

- 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 Terclara 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)

Terclara 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

Terclara 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 Terclara

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. It is unlikely that Terclara 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 Terclara 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

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

Terclara contains propylene glycol

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

3. How to use Terclara

[For medicines available only on prescription:]

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

[For medicines available without prescription:]

Always use this medicine exactly as described in this leaflet or 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 Terclara, 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 Terclara 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.

[For medicines available without prescription:]

You must talk to a doctor if your symptoms do not improve or get worse after 6 months of treatment for fingernails and 9 to 12 months for toenails.

If you use more Terclara 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 Terclara

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 Terclara

Do not stop using Terclara 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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Terclara

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 Terclara 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 Terclara looks like and contents of the pack

Terclara 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

[To be completed nationally]

Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last revised in 2023-06-27