LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Terclara
(terbinafine hydrochloride)

SE/H/2250/001/DC

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terbinafine hydrochloride

Cutaneous solution, 98 mg/ml

This is a summary of the public assessment report (PAR) for Terclara. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Terclara and what is it used for?

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

In Sweden, Terclara can be used without a prescription when the patient has previously been diagnosed by a doctor and the infection does not involve the nail growth zone. The patient may also need to start a new treatment if the infection recovers.

How does Terclara work?

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.

How is Terclara used?

The pharmaceutical form is cutaneous solution for topical use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can be obtained without a prescription in Sweden.

What benefits of Terclara have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in treating mild to moderate fungal infections of the nails caused by dermatophytes and/or other terbinafine sensitive fungi. Terclara is indicated in adults.

What are the possible side effects from Terclara?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Terclara approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Terclara?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Terclara

The full PAR for Terclara can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Terclara , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-09.