

To update the reporting side effects paragraph and to add the information for visually impaired patients

Previously assessed against UK PIL dated June 2013

APPROVED

By A Whitney at 11:25 am, Apr 29, 2019

Mock up

Trosyl® 283mg/ml Nail Solution / Tioconazole 283mg/ml Nail Solution

(tioconazole)

Package Leaflet: Information for the User

Your medicine is known by one of the above names but will be referred to as Trosyl throughout this leaflet.

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

1) What Trosyl is and what it is used for

This medicine contains tioconazole, which is one of a group of medicines called antifungals.

Trosyl is used in adults and children to treat nail infections caused by certain fungi.

2) What you need to know before you use Trosyl

Do not use Trosyl:

- If you have ever had an allergic reaction to tioconazole or any of the other ingredients of this medicine (listed in section 6).
- If you have ever had an allergic reaction to any other medicines you have taken or used to treat fungal infection.
- If you are pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before using Trosyl:

- If you are breast-feeding as you may be told to stop during your treatment.

Make sure you do not put this medicine in your eyes.

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.

3) How to use Trosyl

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

- Apply the nail solution **thinly** to cover the whole of the affected nail(s) and surrounding skin using the brush provided. Apply the solution every 12 hours.
- Leave the solution to dry for 10-15 minutes after application.
- The solution does not dry hard. A transparent, slightly greasy film is left on the nail. This film contains the antifungal agent and it slowly passes through the nail to reach the site of infection.
- The film should be left intact as long as possible. This allows the antifungal agent to have maximum effect.
- Try to avoid putting your hands (or feet if your toenails are affected) in soapy water immediately after applying the solution. Soap or detergent removes the film. Water alone does not remove the film.
- If you need to wash anything by hand, it is best to wear rubber gloves.
- It is usual for treatment to last for up to six months, and in some cases 12 months.

If anyone accidentally swallows this medicine

If you accidentally take this medicine by your mouth, contact your doctor or accident and emergency department straight away.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4) Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people).
Swelling of hands and feet.

Uncommon side effects (may affect up to 1 in 100 people).
Rash, skin irritation around the nails which have been treated. This usually occurs during the first week of treatment and tends to be short-lived and mild.

Not known (frequency cannot be estimated from the available data).
Allergic reaction, which includes itching, dry skin, swelling or blistering of the skin, particularly on the face and around the eyes.

You may also experience nail discolouration, inflammation, pain or burning. You may also feel tingling sensations in the hands or feet or a peeling of the skin.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Trosyl

- Keep all medicines out of the sight and reach of children.
- Do not use Trosyl after the expiry date which is stated on the bottle label and the outer carton. The expiry date refers to the last day of that month.
- Keep away from eyes. Replace cap securely after use.
- Do not store above 30°C. Do not refrigerate. Avoid flame and heat.
- If the nail solution becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6) Contents of the pack and other information

What Trosyl contains

The active substance in Trosyl is tioconazole.
Each ml contains 283mg of the active ingredient tioconazole.

The other ingredients are: ethyl acetate and undecylenic acid.

What Trosyl looks like and contents of the pack

Trosyl is a clear pale yellow solution for topical application contained in an amber glass bottle with a screw cap fitted with an applicator brush.

Each bottle contains 12ml of solution.

PL 10383/2041 Trosyl 283mg/ml Nail Solution /
Tioconazole 283mg/ml Nail Solution

POM

Who makes and repackages your medicine?

Your medicine is manufactured by Farmasierra Manufacturing S.L., Carretera de Irun, Km. 26,200, 28700 San Sebastian de los Reyes, Madrid, Spain. Procured from within the EU and repackaged by the Product Licence Holder: Primecrown Ltd., 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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