

Package leaflet: Information for the patient

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

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 the 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.
- Trosyl should not be diluted or mixed with other agents.
- 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 medicine, 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 or 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 or pain. 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trosyl

- Keep this medicine out of the sight and reach of children.
 - Do not store above 25°C.
 - Avoid flame and heat.
 - Do not refrigerate.
 - Replace cap securely after use
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- Do not use this medicine after the expiry date, which is stated on the carton and the bottle label after EXP. The expiry date refers to the last date of that month.
 - Do not throw away 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 Trosyl contains

The active substance in Trosyl is tioconazole. Each millilitre of this medicine contains 283 mg of tioconazole.

The other ingredients are ethyl acetate and undecylenic acid.

What Trosyl looks like and contents of the pack

Trosyl cutaneous nail solution is a clear pale yellow solution for topical application. It is packaged in a glass bottle with a screw cap fitted with an applicator, containing 12 ml of solution.

Marketing Authorisation Holder:

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,
D04 K7N3
Ireland

Manufacturer:

Farmasierra Manufacturing S.L., Carretera de Irun, Km. 26,200, 28700 San Sebastian de los Reyes, Madrid, Spain.

Company Contact Address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland.
Telephone: 1- 800 633 363

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