

TROSYD®

MYCOTIC AND BACTERIAL SKIN INFECTIONS

28% SOLUTION FOR NAIL CARE

Tioconazole

Carefully read this leaflet in its entirety before using this medicine, as it contains important information for you.

Always use this medicine exactly as described in this leaflet, or as your doctor or pharmacist has instructed you to do.

- Keep this leaflet for your record. You may need to read it again.
- Talk to your pharmacist if you would like more information or advice.
- Talk to your doctor or pharmacist if you get any of the side effects, including effects not listed in this leaflet. See paragraph 4.
- Contact your doctor if you do not notice any improvement, or if your symptoms worsen after a short period of treatment.

This leaflet contains the following information:

1. What is TROSYD and its indications
2. What you need to know before using TROSYD
3. How to use TROSYD
4. Possible side effects
5. How to store TROSYD
6. Box contents and other information

1. WHAT IS TROSYD AND ITS INDICATIONS

TROSYD contains the active ingredient tioconazole, an antifungal used to treat nail infections caused by fungi, such as:

- Onychomycosis caused by dermatophytes and yeasts.
- Mixed nail infections due to concomitant antibacterial (against bacteria) activity.

Contact your doctor if you do not notice any improvement, or if your symptoms worsen after a short period of treatment.

2. WHAT YOU NEED TO KNOW BEFORE USING TROSYD

Do not use TROSYD

- If you are allergic (hypersensitive) to the active ingredient or to any of the other ingredients of this medicine listed in section 6.
- If you are pregnant (see section "Pregnancy and Breastfeeding").

Warnings and Precautions: Talk to your doctor or pharmacist before using TROSYD.

The application of topical medicines, especially if prolonged, can give rise to allergy phenomena (hypersensitivity).

Children and adolescents: There are no data on the safety and efficacy of TROSYD in children and adolescents, consult your doctor.

Other medicines and TROSYD: Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are no known interactions with other drugs.

Pregnancy and breastfeeding: If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Do not use TROSYD during pregnancy because, even if the absorption of the medicine after application on the nails is negligible, treatment can last many months.

Operation of vehicles and machinery: No effect of TROSYD on the ability to operate vehicles and machinery has been reported.

3. HOW TO USE TROSYD

Always use this medicine exactly as described in this leaflet, or as directed by your doctor or pharmacist. If in doubt, consult your doctor or pharmacist. Apply TROSYD on the infected nail and on the periungual region (around the nail) 2 times a day, morning and evening, using the special brush attached to the cap. The solvent contained in TROSYD dries in 5 minutes, leaving a thin clear and oily film. The drug activity does not decrease if the film is unintentionally removed. Do not use an occlusive dressing.

Warning: do not exceed the indicated doses without medical advice.

The duration of the treatment required to achieve healing varies from patient to patient and in relation to the infecting agent and the extent of the lesion. Generally, treatment can last up to 6 months, but also be extended up to a year.

If you use more TROSYD than you should: No cases of overdose have been reported. In case of accidental ingestion/intake of TROSYD, notify your doctor immediately or go to the nearest hospital. If you have additional questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicinal products, this medicine can cause side effects, although not everybody experiences them.

Very rare side effects (may affect up to 1 in 10,000 people) Mild and transient local skin irritation. If you experience allergic reactions (hypersensitivity), discontinue treatment and establish an appropriate therapy. Compliance with the instructions contained in the package leaflet reduces the risk of side effects.

Reporting side effects: If you experience 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 at <http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TROSYD

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the package. The expiry date refers to the last day of the expiry month. This medicine does not require any special storage conditions. Do not throw any medicine in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use.

It will help protect the environment. It is important to have the information about the medicine available at all times, so keep both the box and the package leaflet.

6. BOX CONTENTS AND OTHER INFORMATION

TROSYD contents

100 g of solution contains:

Active ingredient: 28 g tioconazole

Other ingredients: Undecylenic acid, Ethyl acetate.

Description of TROSYD appearance and box contents

Skin solution.

Small bottle containing 12 ml of 28% cutaneous solution for nail care.

Marketing authorisation holder

Giuliani S.p.A. - Via Palagi, 2 - 20129 Milan

Manufacturer

Doppel Farmaceutici - via Martiri delle Foibe, 1 - 29016 Cortemaggiore (PC)

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