

# TROSYD®

## FUNGAL AND BACTERIAL INFECTIONS OF THE SKIN

### 1% CREAM

### 1% SKIN POWDER

### 1% SKIN EMULSION

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 active ingredient tioconazole, an antifungal used to treat skin infections caused by fungi, such as:

- Dermatomycosis caused by dermatophytes, yeasts and other fungi sensitive to tioconazole
- Skin infections caused by drug-sensitive Gram-positive bacteria
- Mixed skin infections due to the concomitant antifungal (against fungi) and 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.

#### 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.

If you are pregnant or breastfeeding, use TROSYD only after consulting your doctor and evaluating with him/her the risk/benefit ratio in your case.

#### Operation of vehicles and machinery

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

**TROSYD 1% cream and 1% emulsion contain cetostearyl alcohol (also called cetylstearyl alcohol). May cause local skin reactions (e.g., contact dermatitis).**

**TROSYD 1% skin emulsion contains propylene glycol. May cause skin irritation.**

### 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 a thin layer of the medicine twice a day (once in the morning and once in the evening) by gently massaging the affected and the area around it.

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

TROSYD 1% Cream: apply the medicine by gently massaging the affected skin and the area around it.

In areas prone to intertrigo (skin folds) the medicine should be applied in small quantities and spread well to avoid maceration phenomena.

TROSYD 1% Skin powder: the medicine is available in a container which allows direct application on an even layer on the affected skin and the area around it.

TROSYD 1% Skin emulsion: apply the medicine by lightly massaging it with your fingertips or with a cotton swab on the affected skin and on the area around it.

The duration of treatment required for healing varies from patient to patient, depending on the infecting agent and the site of infection.

- *Pityriasis versicolor* (fungal infection presenting coffee and milk-coloured spots, usually located on the trunk): a 7-day treatment is usually sufficient to achieve healing in most patients.
- *Tinea pedis (athlete's foot)*: up to 6 weeks of treatment may be required especially for chronic Hyperkeratosis (thickening of the skin).
- *Mycosis in other locations (body, skin folds) candidiasis and erythrasma (bacterial infection)*: the duration of the required treatment is usually between 2 and 4 weeks.

Consult your doctor if the condition occurs repeatedly, or if you have noticed any recent changes in appearance.

#### **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 patients)

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 [www.agenziafarmaco.gov.it/it/responsabili](http://www.agenziafarmaco.gov.it/it/responsabili).

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.

No special storage precautions are required.

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**

###### TROSYD 1% Cream

1 g of cream contains:

**Active ingredient:** Tioconazole: 10 mg

**Other ingredients:** Polysorbate 60, Sorbitan monostearate, Cetostearyl alcohol, 2 Octyldodecanol, Cetyl esters wax, Benzyl alcohol, Purified water.

###### TROSYD 1% Skin powder

100 g of powder contain:

**Active ingredient:** Tioconazole: 1 g

**Other ingredients:** Talc, magnesium myristate, kaolin, precipitated silica.

###### TROSYD 1% Skin emulsion

100 g of emulsion contain:

**Active ingredient:** Tioconazole: 1 g

**Other ingredients:** Emulsifying wax, Cetyl alcohol, Cetylstearyl alcohol, Coconut oil, Glyceryl Palmitate/Stearate, Propylene glycol, Benzyl alcohol, Purified water.

##### **Description of TROSYD appearance and box contents**

###### TROSYD 1% Cream

Cream. 30 g tube

###### TROSYD 1% Skin powder

Skin powder. 30 g bottle

###### TROSYD 1% Skin emulsion

Skin emulsion. 30 g bottle

##### **Marketing authorisation holder**

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

##### **Cream Manufacturer**

Doppel Farmaceutici S.r.l. Via Martiri Delle Foibe, 1- 29016 Cortemaggiore (PC)

##### **Powder and skin emulsion Manufacturer**

Haupt Pharma Latina S.r.l. S.S. 156, Km 50 - 04010 Borgo San Michele (Latina)

**This leaflet was last revised in February 2016**