

Pharmacode IIIIXI

Package leaflet: Information for the user  
**Tioconazole 283 mg/ml Medicated  
Nail Lacquer**

Tioconazole

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

**1. What Tioconazole is and what it is used for**

Tioconazole is one of a group of medicines called antifungals. The active ingredient is tioconazole. Tioconazole is used in adults and children to treat nail infections caused by certain fungi.

**2. What you need to know before you use Tioconazole**

**Do not use Tioconazole:**

- If you are allergic to:
  - Tioconazole or any of the other ingredients of this medicine (listed in section 6)
  - Other imidazole antifungal medicines you have taken to treat a fungal infection.

The symptoms may include itching, reddening of the skin or difficulty in breathing.

- If you are pregnant

**Warnings and precautions:**

Talk to your doctor or pharmacist before using Tioconazole:

- 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. Tioconazole is not for ophthalmic use.

**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 Tioconazole**

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

- Apply the medicated nail lacquer thinly to cover the whole of the affected nail(s) and surrounding skin using the brush provided. Apply the lacquer every 12 hours.
- Leave the lacquer to dry for 10-15 minutes after application.
- The lacquer 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.

The dosage and duration of treatment are the same for children and adults.

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

If anyone accidentally swallows this medicine: If you accidentally take this medicine by your

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mouth, contact your doctor or accident and emergency department straight away.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tioconazole is generally well tolerated. You may experience mild and transient local irritation symptoms (including local allergic reactions) during initial treatment. If you experience an allergic reaction, stop the treatment and consult your doctor.

Anaphylactoid reactions have been reported in patients treated with other formulations than the dermatological preparation.

**Common side effects** (may affect up to 1 in 10 people).

Swelling of hand and feet.

**Uncommon side effects** (may affect up to 1 in 100 people).

Rash and dermatitis.

**Not known** (frequency can not be estimated from the available data)

- Allergic reaction
- Paresthesia (tingling sensations in the hands or feet)
- Blistering of the skin, contact dermatitis, dry skin, swelling around the eyes, nail disorder (including discolouration, inflammation or pain), itch, skin irritation, peeling of the skin, hives and pain.

If you get these symptoms, stop using Tioconazole and tell your doctor or pharmacist.

**Reporting of side effects**

If you get 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:

In the UK via the UK Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

In Ireland to:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

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

**5. How to store Tioconazole**

Inflammable. Avoid flame and heat. Do not refrigerate. Keep the bottle tightly closed. Keep this medicine out of the sight and reach of children.

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 day of that month. The medicated nail lacquer should be used within 6 months after the first opening. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help you protect the environment.

**6. Contents of the pack and other information**

**What Tioconazole contains**

The active substance is tioconazole. One ml of product contains 283 mg of tioconazole. The other ingredients are ethyl acetate and undecylenic acid.

**What Tioconazole looks like and contents of the pack**

Tioconazole is a clear solution for cutaneous use. Tioconazole is contained in an amber type III soda-lime silica glass bottle with a HDPE/LDPE screw cap fitted with a nylon brush applicator containing 12 ml.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Creo Pharma Limited, Felsted Business Centre, Felsted, Essex CM6 3LY, UK

Manufacturer:

Doppel Farmaceutici S.r.L.,

Via Martiri delle Foibe, 1,

29016 Cortemaggiore (PC), Italy

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| PIL Format    | 150 x 170 mm                 | Country | UK              |
| Initial Code  |                              | Job No. | CRE-TIO-PIL-132 |
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