

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Trosyl 283 mg/ml Nail Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 283 mg tioconazole.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution

Product imported from Italy:

A clear, pale yellow solution for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Trosyl Nail Solution is indicated for the topical treatment of nail infections due to fungi (superficial dermatophytes and yeasts) susceptible to this anti-infective.

4.2 Posology and method of administration

Adults: The solution should be applied to the affected nails and immediately surrounding skin every twelve hours using the applicator brush supplied.

The duration of treatment is up to six months but may be extended to twelve months.

Use in the elderly: No special precautions are required. Use the adult dose.

Use in children: No special precautions are required. Use the adult dose.

The solution should be left to dry for 10-15 minutes after the application.
A transparent, greasy film is left of the nail. The film should be left intact as long as possible.

4.3 Contraindications

Trosyl Nail Solution is contra-indicated in individuals who have been shown to be hypersensitive to imidazole antifungal agents, or to any of the components of the solution.

Use is contraindicated during pregnancy

4.4 Special warnings and precautions for use

Trosyl Nail Solution is not for ophthalmic use.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Use During Pregnancy:

In animal studies tioconazole was not teratogenic. At high doses it increased the incidence of renal abnormalities in rat embryos, but this effect was minor and transient and was not evident in weaned animals. There is insufficient evidence as to the drug's safety in human pregnancy although absorption after topical administration is negligible. Because of the extensive duration of treatment required for nail infections, the use of Trosyl Nail Solution is contra-indicated throughout pregnancy.

Use During Lactation:

It is unknown whether this drug is excreted in human milk. Because many drugs are excreted in human milk, nursing should be temporarily discontinued while Trosyl is administered.

4.7 Effects on ability to drive and use machines

Trosyl Nail Solution has no or negligible influence.

4.8 Undesirable effects

Trosyl Nail Solution is well tolerated following local application. Symptoms of local irritation have been reported by some patients, but are usually seen during the first week of treatment and are transient and mild. Systemic allergic reactions are uncommon.

However, if a sensitivity reaction develops with the use of Trosyl Nail Solution, treatment should be discontinued and appropriate therapy instituted.

System Organ Class	Frequency	Undesirable effects
Immune system disorders	Unknown	Allergic reaction
Nervous system disorders	Unknown	Paresthesia
Skin and subcutaneous tissue disorders	Unknown	Bullous eruption, dermatitis contact, dry skin, edema periorbital, nail disorder (including nail discoloration, periungual inflammation and nail pain), pruritis, skin irritation, skin exfoliation, urticaria
	Uncommon	Dermatitis, rash,
General disorders and administration site conditions	Common	Edema peripheral
	Unknown	Pain

4.9 Overdose

No cases of overdosage with Trosyl Nail Solution have been reported. In the event of excessive oral ingestion, gastrointestinal symptoms may occur. Appropriate means of gastric lavage should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives.
ATC Code: D01AC07.

Tioconazole is an imidazole which is active against commonly occurring dermatophyte and yeast-like fungal species. It is fungicidal in murine models vs. *Candida* spp., *T. rubrum* and *T. mentacrophytes*. *In vitro* it is fungicidal to pathogenic dermatophytes, yeasts and other fungi. All dermatophytes and *Candida* spp. were inhibited by 6.25 or 12.5 mg/l respectively. It is also inhibitory vs. *Staph.* spp. and *Strep.* spp. at 100 mg/l or less.

Oral doses (200 mg/kg) did not affect behaviour in rats but 25 mg/kg i.v. produced dose-related respiratory distress, gasping, tremors and prostration. Slight but dose-related impairment of performance of mice on the rotating rod occurred from 25 mg/kg. Slight anti-cholinergic and anti-histamine (H₁) activity was recorded *in vitro* but no effect on mice pupil size *in vivo*. Oral tioconazole prolonged alcohol and pentobarbital sleeping time at 150 and 37.5 mg/kg respectively.

In the anaesthetised cat i.v. tioconazole 2.5 - 10 mg/kg produced brief falls in blood pressure and increased heart rate, haematuria, tremors and twitches.

5.2 Pharmacokinetic properties

Absorption is rapid and extensive on oral administration to rats, monkeys and man, the major metabolite being a glucuronide conjugate of tioconazole. Tissue uptake in rat and monkey was highest in liver, kidney and intestinal tract with excretion in all species mainly in faeces.

Rat studies using oral, dermal and vaginal administration of C¹⁴ labelled tioconazole confirm significantly lower absorption via the topical route.

In man, oral formulations of tioconazole (500mg) gave plasma concentrations of 1300ng/ml. Topical administration of dermal cream 1% (20mg/day) for 28 days, or vaginal cream 2% (100mg/day) for 30 days gave negligible mean peak plasma levels, i.e. 10.1 and 11.5ng/ml respectively.

After single dose administration of tioconazole vaginal ointment 6.5% w/w (tioconazole 300mg) the mean peak plasma concentration was 18ng/ml in humans, achieved approximately 8 hours post dose.

5.3 Preclinical safety data

None relevant to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Undecylenic acid
Ethyl acetate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the bottle label and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Avoid flame and heat. Do not refrigerate.

6.5 Nature and contents of container

Trosyl Nail Solution is contained in an amber glass bottle containing 12ml with a screw cap fitted with a brush.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Trosyl should not be mixed with other agents. Dilution is not appropriate.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

G & A Licensing Limited
Ballymurray
Co. Roscommon

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1447/43/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th December 2009

10 DATE OF REVISION OF THE TEXT