Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Trosyl 283 mg/ml Nail Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tioconazole 283 mg/ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
A clear pale yellow solution for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Tioconazole is a broad spectrum imidazole antifungal agent. Trosyl Nail Solution is indicated for the topical treatment of nail infections due to susceptible fungi (dermatophytes and yeasts) and bacteria.

4.2 Posology and method of administration

Route of administration: Topical.

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

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Trosyl Nail Solution is contraindicated in individuals who have been shown to be hypersensitive to imidazole antifungal agents.

Use is contraindicated during pregnancy (see section 4.6).

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

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.

Breast-feeding
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

None known.

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.

The undesirable effects listed below were reported with frequencies corresponding to
Common (≥1/100, ≤1/10), Uncommon (≥1/1000, <1/100), Rare (≥1/10,000 to
<1/1,000), or Very rare (<1/10,000) not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class
Immune system disorders
Nervous system disorders
Skin and subcutaneous tissue disorders

General disorders andadministration site conditions

Frequency	**Undesirable effects**
Unknown	Allergic reaction
Unknown	Paraesthesia
Unknown	Bullous eruption, dermatitiscontact, dry skin, edema periorbital, nail disorder(including nail discoloration,periungual inflammation and nailpain), pruritis, skin irritation,skin exfoliation, urticaria
Uncommon	Uncommon Dermatitis, rash
Common	Oedema peripheral
Unknown	Pain

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected

adverse reactions 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.

4.9 Overdose

No cases of overdosage with Trosyl Nail Solution have been reported. Overdosage by topical application of tioconazole is unlikely because of negligible systemic absorption.
In the event of excessive oral ingestion by mistake, 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 (H_1) 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
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 C^{14} 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.

Distribution
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

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Avoid flame and heat. Do not refrigerate. Replace cap securely after use.

6.5 Nature and contents of container

Trosyl Nail Solution is contained in an amber glass bottle with a HDPE screw cap fitted with an LDPE brush system and polyamide brush bristle applicator containing 12 ml.

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

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
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8 MARKETING AUTHORISATION NUMBER

PA0822/197/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 06 February 2010

10 DATE OF REVISION OF THE TEXT

December 2024