

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Trosyl 283mg/ml Nail Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 283mg 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

As per PA0019/030/006

5 PHARMACOLOGICAL PROPERTIES

As per PA0019/030/006

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 container and outer package of the product 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. Replace cap securely after use.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

Not Applicable

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex, HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/156/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th June 2011

10 DATE OF REVISION OF THE TEXT

October 2014