

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

Product imported from Spain

A clear pale-yellow solution for topical application

4 CLINICAL PARTICULARS

As per PA0822/197/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/197/001

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 for this product shall be the date shown on the bottle 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, 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st July 2020

10 DATE OF REVISION OF THE TEXT

February 2022