

# 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 *Portugal*

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 of this product shall be the date shown on the container 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. Store in the original package.

### 6.5 Nature and contents of container

Trosyl Nail Solution is contained in an amber glass bottle with a screw cap fitted with a brush system 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 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/169/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 24<sup>th</sup> August 2021

**10 DATE OF REVISION OF THE TEXT**