

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Loceryl 5% w/v Medicated Nail Lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Loceryl Nail Lacquer contains 5% w/v amorolfine in the form of amorolfine hydrochloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Nail Lacquer

Product imported from Greece:

A clear colourless to almost colourless liquid

4 CLINICAL PARTICULARS

As per PA22743/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22743/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methacrylic acid copolymer 150,000

Triacetin

Butyl acetate

Ethyl acetate

Ethanol Anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Store below 30 °C.

Protect from heat.

Keep bottle tightly closed after use.

6.5 Nature and contents of container

Amber glass bottle with screw thread and plastic screw closure.

All packs contain cleansing swabs, spatulas and nail files.

Pack size: 5.0 ml (1 x 5.0ml)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/234/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2009

10 DATE OF REVISION OF THE TEXT

August 2023