

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.

Excipient with known effect:

alcohol (ethanol)

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

Solvent (on the tissue): isopropyl alcohol 70%.

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.

After first opening the bottle with spatula incorporated in screw cap use within 3 months.

6.4 Special precautions for storage

Store below 30 °C. Protect from heat. Keep the bottle tightly closed after use.

6.5 Nature and contents of container

Amber glass bottle with screw thread and plastic screw closure.
Packs contain cleansing swabs, nail files and spatula integrated in the cap.
Pack size: 5 ml (1 x 5 ml)

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/081/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th October 2013

10 DATE OF REVISION OF THE TEXT

July 2023