

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:

One gram of nail lacquer 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

Triacetin

Acetate butyl ester

Ethyl acetate

Absolute alcohol

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.

Shelf life after first opening: 3 months

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 type III bottle with screw thread and plastic screw closure with integrated applicator.

Pack sizes: 5.0ml (1 x 5.0 ml)

All packs contain cleansing swabs and nail files.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/036/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th October 2020

10 DATE OF REVISION OF THE TEXT

December 2023