

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 The UK

A clear colourless to almost colourless liquid.

4 CLINICAL PARTICULARS

As per PA0590/018/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0590/018/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonio methacrylate copolymer A

Triacetin

Butyl acetate

Ethyl acetate

Ethanol

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 carton of the product as marketed 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 cleaning swabs, spatulas and nail files.

Or

Amber glass bottle with screw thread and plastic screw closure with integrated applicator. All packs contain cleansing swabs and nail files.

Pack size: 5.0 ml (1 x 5.0 ml)

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

Imbat Ltd.
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/214/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 2013

10 DATE OF REVISION OF THE TEXT

April 2018