

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 a 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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

Loceryl nail lacquer should be stored below 30°C. Protect from heat. Keep bottle tightly closed after use.

6.5 Nature and contents of container

Amber glass type I bottle with screw thread and plastic screw closure.

Pack sizes: 5.0ml (1 x 5.0 ml)
All packs contain cleansing swabs, spatulas and nail files.

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.

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

September 2017