

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 anhydrous

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.

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 size 5.0ml (1 x 5.0 ml)

The pack contains 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

LTT Pharma Limited
Unit 18, Oxleasow Road
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B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/053/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd June 2011

10 DATE OF REVISION OF THE TEXT

November 2015