

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 amorolofine 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 Anhydrous

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 threat and plastic screw closure in an overlabelled outer carton.

Pack sizes: 5ml.
All packs contain cleansing swabs, spatulas, and nail files.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/234/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2009

10 DATE OF REVISION OF THE TEXT

June 2016