

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lescol XL 80 mg Prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: fluvastatin (as fluvastatin sodium)

One prolonged release tablet of Lescol contains 84.24 mg fluvastatin sodium equivalent of 80 mg Fluvastatin free acid.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablet

Product imported from the Czech Republic

Yellow round, slightly biconvex film-coated tablet with bevelled edges, approx. 10mm in diameter, debossed with “LE” on one side/”NVR” on the other.

4 CLINICAL PARTICULARS

As per PA0013/053/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/053/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Cellulose microcrystalline
Hypromellose
Hydroxypropyl cellulose
Potassium hydrogen carbonate
Povidone
Magnesium stearate

Coating

Hypromellose
Macrogol 8000
Iron oxide yellow (E172)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package to protect from light and moisture.

6.5 Nature and contents of container

Pack of 28 tablets in blister strips.

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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/039/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th November 2010

10 DATE OF REVISION OF THE TEXT

December 2016