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 XL contains 84.24 mg fluvastatin sodium equivalent to 80 mg fluvastatin free acid.

Excipient: For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release tablet.

Product imported from Czech Republic and France:
Yellow, round, slightly biconvex film-coated tablet with bevelled edges, approx. 10 mm in diameter, debossed with "LE" on one side/"NVR" or Nil on the other.

4 CLINICAL PARTICULARS

As per PA23517/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23517/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline
Hypromellose
Hydroxypropyl cellulose
Potassium hydrogen carbonate
Povidone
Magnesium stearate
Macrogol 8000
Iron oxide yellow (E172)
Titanium dioxide (E 171)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product shall be 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

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

6.5 Nature and contents of container

Pack size: 28 or 30 prolonged-release tablets in blisters contained in a carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/404/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

March 2024