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)

Each prolonged-release tablet contains 84.24 mg of fluvastatin sodium equivalent to 80 mg fluvastatin free acid.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

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

4 CLINICAL PARTICULARS

As per PA23517/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23517/001/001

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 (E 171)

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 carton 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 prolonged-release tablets in blisters contained in a labelled carton.

6.6 Special precautions for disposal and other handling

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

PPA1463/101/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2015

10 DATE OF REVISION OF THE TEXT

September 2023