Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Crestor 10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg rosuvastatin (as rosuvastatin calcium).

Excipient(s) with known effect: Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Italy, Romania and Belgium
Round, pink coloured tablets, intagliated with 'ZD4522' and '10' on one side and plain on the reverse.

4 CLINICAL PARTICULARS

As per PA2242/016/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/016/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Lactose monohydrate
Microcrystalline cellulose
Calcium phosphate
Crospovidone
Magnesium stearate

Tablet coat
Lactose monohydrate
Hypromellose
Triacetin
Titanium dioxide (E171)
Ferric oxide, red (E172)

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

Store below 30 °C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blisters of 28 tablets in a carton.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/441/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th October 2018

10 DATE OF REVISION OF THE TEXT

December 2023