Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Crestor 40 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 40 mg rosuvastatin (as rosuvastatin calcium).
Excipient(s) with known effect: lactose monohydrate.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Italy
Oval, pink coloured film-coated tablets, intagliated with 'ZD4522' on one side and '40' on the reverse.

4 CLINICAL PARTICULARS

As per PA2242/016/004

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/016/004

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)
Iron oxide red (E172)

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

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

6.6 Special precautions for disposal

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

PPA1463/119/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th February 2022

10 DATE OF REVISION OF THE TEXT

October 2023