Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Crestor 20 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg rosuvastatin (as rosuvastatin calcium).

Excipient with known effect
Contains lactose monohydrate
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
Product imported from Italy
Round, pink coloured tablets, marked with 'ZD4522' and '20' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA1019/009/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/009/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Calcium phosphate
Crospovidone
Magnesium stearate
Hypromellose
Triacetin
Titanium dioxide (E171)
Red iron oxide (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 blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

For product procured from UK and Belgium: Do not store above 30°C. Store in the original package.
For product procured from Romania, Czech Republic and Poland: Store below 30°C. Store in the original package.
Product imported from Italy: 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/044/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 9th November 2007

10 DATE OF REVISION OF THE TEXT

April 2019