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 20.80 mg 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 Romania
Round, pink coloured tablets, intagliated with 'ZD4522' and '20' on one side and plain on the reverse.

4 CLINICAL PARTICULARS

As per PA2242/016/003

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/016/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
lactose monohydrate,
microcrystalline cellulose,
calcium phosphate,
crospovidone,
magnesium stearate

Tablet coat
lactose monohydrate,
hypromellose,
glycerol triacetate,
titanium dioxide (E 171),
red iron oxide (E 172).

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

Box of 2 Al/Al blister packs of 14 film-coated tablets each.

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

Originalis B.V.,
Joop Geesinkweg 901,
1114 AB Amsterdam-Duivendrecht,
The Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th September 2024

10 DATE OF REVISION OF THE TEXT