Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atorvastatin 20mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg atorvastatin as atorvastatin calcium.

Excipient with known effect:
Each 20 mg film-coated tablets contains lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK:
White, round (diameter = 8 mm), slightly convex, bevel-edged.

4 CLINICAL PARTICULARS

As per PA1347/023/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1347/023/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Lactose monohydrate
Magnesium stearate
Sodium laurilsulfate
Microcrystalline cellulose
Crospovidone
Hydroxypropylcellulose
Croscarmellose sodium
Sodium hydroxide

Coating:
Polyvinyl alcohol
Titanium dioxide (E171)
Macrogol 3000
Talc

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

This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister pack: 28 film-coated tablets in a cardboard box.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10
Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/051/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th November 2014

10 DATE OF REVISION OF THE TEXT

April 2016