Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atorvastatin 80mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 80 mg atorvastatin as atorvastatin calcium.

Excipient with known effect:
Each 80 mg film-coated tablet contains lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK:
White to almost white, capsule shape, biconvex, film-coated tablets, tablet dimensions 18 mm x 9 mm.

4 CLINICAL PARTICULARS

As per PA1347/023/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1347/023/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Sodium hydroxide
Hydroxypropylcellulose (E463)
Lactose monohydrate
Microcrystalline cellulose (E460)
Croscarmellose sodium
Type A crospovidone
Polysorbate 80
Magnesium stearate (E572)

Film-coating:
Opadry II White 85F28751 containing:
Polyvinyl alcohol
Titanium dioxide (E171)
Macrogol 3000
Talc (E553b)

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

6.5 Nature and contents of container

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

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/051/004

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