

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 of atorvastatin (as atorvastatin calcium).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK:

White to off-white, elliptic, biconvex and smooth film-coated tablets. The dimensions of each tablet are approximately 18.8mm x 10.3mm.

4 CLINICAL PARTICULARS

As per PA0749/110/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/110/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Microcrystalline cellulose
Sodium carbonate anhydrous
Maltose
Croscarmellose sodium
Magnesium stearate

Film-Coating:

Hypromellose (E464)
Hydroxypropylcellulose
Triethyl citrate (E1505)
Polysorbate 80
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 below 30°C.

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 material 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

PPA0565/061/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 2015

10 DATE OF REVISION OF THE TEXT