

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Atorvastatin 20mg film-coated tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 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 12.5mm x 6.6mm.

### 4 CLINICAL PARTICULARS

As per PA0749/110/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0749/110/002

### 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**

PPA0565/061/002

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 12<sup>th</sup> June 2015

### **10 DATE OF REVISION OF THE TEXT**