

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Atorvastatin 40mg film-coated tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 40 mg atorvastatin as atorvastatin calcium.

Excipient with known effect:

Each 40 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, round (diameter = 10 mm), slightly convex, bevel-edged.

### 4 CLINICAL PARTICULARS

As per PA1347/023/003

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1347/023/003

### 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**

PPA0565/051/003

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

Date of first authorisation: 7<sup>th</sup> November 2014

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

April 2016