

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Crestor 5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg rosuvastatin (as rosuvastatin calcium).

### Excipient with known effect

Each tablet contains lactose monohydrate.

For the full list of excipients see Section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Italy*

Round, yellow coloured tablets, marked with 'ZD4522' and '5' on one side and plain on the reverse.

## 4 CLINICAL PARTICULARS

As per PA1019/009/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/009/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate  
Microcrystalline cellulose  
Calcium phosphate  
Crospovidone  
Magnesium stearate  
Hypromellose  
Triacetin  
Titanium dioxide (E171)  
Yellow iron oxide (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

#### **6.4 Special precautions for storage**

Store below 30 °C.

Store in the original package in order to protect from moisture.

#### **6.5 Nature and contents of container**

Blisters of 28 tablets.

#### **6.6 Special precautions for disposal**

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

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/044/003

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

Date of first authorisation: 27th March 2013

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

April 2019