

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Crestor 10 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg rosuvastatin (as rosuvastatin calcium).

Excipient(s) 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, pink coloured tablets, intagliated with 'ZD4522' and '10' on one side and plain on the reverse.

## 4 CLINICAL PARTICULARS

As per PA1019/009/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/009/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Tablet core

Lactose monohydrate  
Microcrystalline cellulose  
Calcium phosphate  
Crospovidone  
Magnesium stearate

#### Tablet coat

Lactose monohydrate  
Hypromellose  
Triacetin  
Titanium dioxide (E171)  
Iron oxide red (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for 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**

Blisters: 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**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

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

PPA1463/119/002

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

Date of first authorisation: 27<sup>th</sup> April 2018

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

November 2021