

# 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

Lactose monohydrate  
Microcrystalline cellulose  
Calcium phosphate  
Crospovidone  
Magnesium stearate  
Hypromellose  
Triacetin  
Titanium dioxide (E171)  
Ferric oxide, red (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 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. Store in the original package in order to protect from moisture.

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

Blisters of 28 tablets in a carton.

## **6.6 Special precautions for disposal and other handling**

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

## **7 MARKETING AUTHORISATION HOLDER**

PCO Manufacturing  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PPA0465/441/002

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/441/002

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

Date of first authorisation: 12<sup>th</sup> October 2018

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

December 2019