

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lipitor 80 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 80 mg atorvastatin (as atorvastatin calcium trihydrate).

### Excipient(s) with known effect:

Each Lipitor 80 mg film-coated tablet contains lactose monohydrate and benzoic acid.

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Italy Spain, Poland and Czech Republic*

White elliptical tablet debossed '80' on one side and 'PD 158' on the other side **or** white and round with '80' on one side and 'ATV' on the other.

## 4 CLINICAL PARTICULARS

As per PA23055/017/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23055/017/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Tablet Core:

Calcium carbonate,  
Microcrystalline cellulose  
Lactose monohydrate  
Croscarmellose sodium  
Polysorbate 80  
Hyprolose  
Magnesium stearate

#### Film coat:

Film coating containing:  
Hypromellose  
Macrogol 8000  
Titanium dioxide (E171)  
Talc

#### Simethicone emulsion containing:

##### Simethicone

Stearate emulsifiers (polyethylene glycol sorbitan tristearate, polyethoxylate stearate, glycerides)  
Thickeners (methylcellulose, xanthan gum)  
Benzoic acid (E 210)  
Sorbic acid

Sulfuric acid

## **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**

This medicinal product does not require any special storage precautions.

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

Blister pack of 28 and 30 tablets contained in an outer cardboard carton.

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

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/075/004

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

Date of first authorisation: 29 July 2005  
Date of last renewal: 29 July 2010  
Last updated: January 2016  
Last updated: July 2020

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

July 2022