

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 tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from the UK, Italy, Spain, France and Poland:

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 PA1740/001/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1740/001/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

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

Coating:

Hypromellose
Macrogol 8000
Titanium dioxide (E171)
Talc
Simethicone
Stearate emulsifiers
Sorbic acid

May also contain Stearate emulsifiers (Polyethylene glycol sorbitan tristearate, Polyethoxylate stearate, Glycerides), Thickeners (Methylcellulose, Xanthan gum) and Benzoic 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

10 DATE OF REVISION OF THE TEXT

October 2020