

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipitor 40 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 40 mg atorvastatin (as atorvastatin calcium trihydrate).

Excipient(s) with known effect:

Each Lipitor 40mg film-coated tablet contains Lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

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

White oval shaped, film-coated tablet with '40' on one side and 'PD 157' on the other side or white and round with '40' on one side and 'ATV' on the other.

4 CLINICAL PARTICULARS

As per PA1740/001/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1740/001/003

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

May also contain Candelilla wax, 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 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs containing 28 or 30 tablets contained in an outer cardboard carton.
Not all pack sizes may be marketed.

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

PPA0465/075/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 2001

Date of last renewal: 13 July 2006

Last updated: January 2016

10 DATE OF REVISION OF THE TEXT

October 2020