

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipitor 10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg atorvastatin (as atorvastatin calcium trihydrate).

Excipient(s) with known effect:

Each Lipitor 10mg film coated ablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from Belgium, Greece, the Netherlands, the UK, Germany Italy, France Spain & Poland

White oval shaped, film-coated tablet with '10' on one side and 'PD 155' on the other side or white and round with '10' on one side and 'ATV' on the other

4 CLINICAL PARTICULARS

As per PA1740/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1740/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core

Calcium carbonate,
microcrystalline cellulose,
lactose monohydrate,
croscarmellose sodium,
polysorbate 80,
hyprollose ,
magnesium stearate,

Film-coat

Film coating containing:
hypromellose,
Macrogol 8000,
titanium dioxide (E171),
talc,
simeticone,
stearate emulsifiers,
sorbic acid,

May also contain Candelilla wax, Stearate emulsifiers (polyethylene glycol sorbitan tristearate, polyethoxylate stearate, glycerides), Thickeners (methylcellulose, xantan 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 precautions.

6.5 Nature and contents of container

Blister packs of 14, 28 or 30 film-coated tablets contained in an outer cardboard carton.
Not all pack sizes may be marketed.

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

PPA0465/075/001

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