

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 10 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 tablets

Product imported from Belgium, Greece, the Netherlands, Germany, Italy, France, Spain, Poland and Czech Republic

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 PA23055/017/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/017/001

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,

Simeticone emulsion containing:

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

Sulfuric acid

May also contain Candelilla wax

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
Last updated: July 2020

10 DATE OF REVISION OF THE TEXT

September 2022