

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipitor 10mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10mg atorvastatin as atorvastatin calcium trihydrate.
Excipients: Each film-coated tablet also contains lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from UK and Spain:

White, elliptical tablets debossed '10' on one side and 'PD 155' on the other side.

or

White, circular shaped, film-coated tablet marked '10' on one side and 'ATV' on the other side.

4 CLINICAL PARTICULARS

As per PA1740/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1740/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from the UK:

Calcium carbonate

Microcrystalline cellulose

Lactose monohydrate

Croscarmellose sodium

Polysorbate 80

Hydroxypropyl cellulose

Magnesium stearate

Hypromellose

Macrogol 8000

Titanium dioxide

Talc

Simeticone

Macrogol stearate

Sorbic acid

Stearate emulsifiers*

Thickeners*

Benzoic acid*

Candelilla wax**

- * circular shaped tablet only
- **elliptical shaped table only

Product imported from Spain:

Calcium carbonate
Microcrystalline cellulose
Lactose monohydrate
Croscarmellose sodium
Polysorbate 80
Hydroxypropyl cellulose
Magnesium stearate
Hypromellose
Macrogol 8000
Titanium dioxide
Talc
Simeticone
Stearate emulsifiers
Sorbic 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 blister strip 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

Cardboard carton containing 4 blister strips (7 tablets per strip).
Pack size: 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/005/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th of September 2010

10 DATE OF REVISION OF THE TEXT

May 2016