Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipitor 20 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 mg atorvastatin (as atorvastatin calcium trihydrate).
Excipient(s) with known effect:
Each Lipitor 20 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, Spain, France, Poland and Czech Republic
White oval shaped, film-coated tablet with '20' on one side and 'PD 156' on the other side White and round with '20' on one side and 'ATV' on the other

4 CLINICAL PARTICULARS

As per PA23055/017/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/017/002

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

Simethicone emulsion containing:
Simethicone,
Stearate emulsifiers (polyethylene glycol, sorbitan tristearate, polyethoxylated 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 conditions

6.5 Nature and contents of container

Blister packs containing 14, 28 or 30 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

PPA0465/075/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th of July 2001
Date of last renewal: 13th July 2006
Last updated: January 2016
Last updated: July 2020

10 DATE OF REVISION OF THE TEXT

July 2022