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 tablet contains 27.25 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK

White round, 5.6 mm, film-coated tablets debossed ‘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

Tablet core:
Calcium carbonate
Microcrystalline cellulose
Lactose monohydrate
Croscarmellose sodium,
Polysorbate 80
Hydroxypropyl cellulose
Magnesium stearate

Film coat:
Film coating containing:
Hypromellose
Macrogol 8000
Titanium dioxide (E171)
Talc

Simethicone Emulsion containing
simethicone, stearate emulsifiers, (polyethylene glycol sorbitan tristearate, polyethoxylate stearate, glycerides)
Thickeners (methylcellulose, xanthan gum)

Benzoic acid
Sorbic acid
sulfuric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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 tablets contained in an outer cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/099/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th May 2013

10 DATE OF REVISION OF THE TEXT

August 2017