Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipitor 80 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 86.76 mg atorvastatin calcium trihydrate, equivalent to 80 mg atorvastatin.

Excipient(s) with known effects:
Each Lipitor 80 mg film-coated tablet contains 218.00 mg lactose monohydrate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK
White, round, film-coated tablets debossed ‘80’ on one side and ‘ATV’ on the other side.

4 CLINICAL PARTICULARS

As per PA1740/001/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1740/001/004

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 (methyl cellulose, 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

Lipitor film-coated tablets are available in blister packs containing 28s

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

PPA1562/099/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th May 2013

10 DATE OF REVISION OF THE TEXT

July 2017