

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 54.50 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, 7.1 mm, film-coated tablets debossed '20' on one side and 'ATV' on the other.

4 CLINICAL PARTICULARS

As per PA1740/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1740/001/002

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 carton 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 28 film-coated tablets

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

PPA1562/099/002

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