Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Adalat LA 60 mg Prolonged-Release Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 60 mg nifedipine.

Excipient(s) with known effect:
Each tablet contains Sodium.
For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release film-coated tablet.

Product imported from the UK and Spain:
Pink, circular convex tablets with "Adalat 60" marked on one side and a laser hole on the other side.

4 CLINICAL PARTICULARS

As per PA1410/025/007

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/025/007

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Cellulose acetate
Hypromellose
Hydroxypropylcellulose
Polyethylene oxide
Macrogol
Magnesium stearate
Titanium dioxide (E171)
Iron oxide (E172)
Sodium chloride (salt)

Product imported from the UK also contains:
Shellac

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

Do not store above 30°C. Store in the original container in order to protect from light and moisture.

6.5 Nature and contents of container

Blister strips of 2 x 14 tablets. Blister packs composed of PP backed with aluminium foil.
Pack size: 28 tablets.

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

PPA1562/036/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th November 2010

10 DATE OF REVISION OF THE TEXT

December 2016