Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Adalat LA 60 mg Prolonged-release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 60 mg of nifedipine.

Excipients: Sodium

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release film-coated tablet
Product imported from The Netherlands, Greece and Spain;
Pink, lacquered tablets printed ‘Adalat 60’ in black on one side, plain on the other side.

4 CLINICAL PARTICULARS

As per PA 1410/025/007

5 PHARMACOLOGICAL PROPERTIES

As per PA 1410/025/007

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients present in the product imported from The Netherlands:

Polyethylene oxide
Hypromellose
Magnesium stearate
Sodium chloride
Iron oxide red (E172)
Cellulose acetate
Macrogol
Hyprolose
Propylene glycol
Titanium dioxide (E171)
Printing ink (shellac, iron oxide black (E172))

Excipients present in the product imported from Greece:

Polyethylene oxide
Hypromellose
Magnesium stearate
Sodium chloride
Iron oxide red (E172)
Cellulose acetate

Macrogol 4000
Propylene glycol
Titanium dioxide (E171)

Excipients present in the product imported from Spain:

Polyethylene oxide
Hypromellose
Magnesium stearate
Sodium chloride
Iron oxide red (E172)
Cellulose acetate
Macrogol
Hyprolose
Propylene glycol
Titanium dioxide (E171)
Iron oxide black (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Do not store above 25°C. Store in the original container. The tablets should be protected from strong light.

6.5 Nature and contents of container

Blister packs containing 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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/012/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th December 2001
Date of last renewal: 14th December 2006

10 DATE OF REVISION OF THE TEXT

September 2016