Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Adalat LA 60mg Prolonged-release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release Film-coated tablet contains 60 mg nifedipine.
Each tablet contains sodium.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release, Film-coated tablets.

Product imported from Greece:
Pink, circular biconvex tablets with ‘Adalat 60’, printed with black ink on one 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
Polyethylene oxide
Macrogol
Magnesium stearate
Hyprolose
Titanium dioxide (E171)
Iron oxide, red (E172)
Sodium chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be 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^{o}C.
Store in the original package.
The tablets should be protected from strong light and moisture.

6.5 Nature and contents of container

Blister packs composed of PP backed with aluminium foil, each 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

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/047/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 13th October 2006

Date of Last Renewal: 13th October 2011

10 DATE OF REVISION OF THE TEXT

July 2015