Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Adalat LA 20mg Prolonged-release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 20mg of nifedipine.
Each tablet contains 8.3mg sodium.

For a full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM

Prolonged-release, film-coated tablet.

Product imported from the UK and Greece:
Pink, circular convex tablets with Adalat 20 marked on one side.

4 CLINICAL PARTICULARS

As per PA1410/025/005

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/025/005

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

Product imported from the UK also contains Shellac.

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

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/012/007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 December 2005

Date of last renewal: 22 December 2010

10 DATE OF REVISION OF THE TEXT

January 2016