Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Adalat LA 30mg Prolonged-Release Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 30 mg nifedipine.
Excipient with known effect: Sodium
For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release film-coated tablet.

Product imported from the UK, Romania and Spain:
Pink, circular, convex tablets with 'Adalat 30' marked on one side and plain on the reverse.

4 CLINICAL PARTICULARS

As per PA1410/025/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/025/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from the UK and Romania:

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

(* in product sourced from the UK only).

Product imported from Spain:

Polyethylene oxide
Hypromellose
Magnesium stearate
Sodium chloride
Red iron oxide (E172)

Cellulose acetate
Macrogol
Hydroxypropylcellulose
Propylene glycol
Titanium dioxide (E171)
Black iron oxide (E172)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Product sourced from Spain: Do not store above 30°C.
Store in the original package in order to protect from light and moisture.

Product sourced from Romania & UK: Do not store above 30°C.
Store in the original container. Protect from strong light.

6.5 Nature and contents of container

Over-labelled outer carton containing blister strips.
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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/047/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th June 2009

10 DATE OF REVISION OF THE TEXT

December 2016