Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Adalat Retard 20 mg Prolonged-Release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated, prolonged-release tablet contains 20 mg nifedipine.

Excipients: Lactose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated, prolonged-release tablets

Product imported from Spain:
Grey-pink, circular, film-coated, prolonged-release tablets marked ‘A20’ on one side with the Bayer Cross on the reverse.

4 CLINICAL PARTICULARS

As per PA1410/025/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/025/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Maize starch
Lactose
Polysorbate 80
Magnesium stearate
Hypromellose
Macrogol 4000
Titanium dioxide (E 171)
Red iron oxide (E 172)

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

Store in the original container in order to protect from light.
Keep container in the outer carton.

6.5 Nature and contents of container

Blister strips of tablets in a cardboard outer container, in packs of 60 tablets.

Pack size: 60 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 Moon Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/036/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th November 2010

10 DATE OF REVISION OF THE TEXT

August 2015