

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.

Excipients: Sodium

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged-release film-coated tablet.

Product imported from Romania:

Pink, circular convex tablets with Adalat 30 marked on one side.

4 CLINICAL PARTICULARS

As per PA1410/025/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/025/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose (5cP)

Magnesium stearate

Polyethene oxide

Iron oxide red (E172)

Sodium chloride

Ethyl cellulose

Macrogol (3350)

Hydroxypropyl cellulose

Hypromellose (3cP)

Titanium dioxide (E171)

Propylene glycol

black ink lettering

Shellac

Black iron oxide (E172)

Propylene glycol

Ammonium hydroxide 28%

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 30°C. Store in the original container. The tablets should be protected from strong light. Do not remove the tablet from the blister until immediately before use.

6.5 Nature and contents of container

Blisters packed into a cardboard carton of 28 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast
BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st January 2011

10 DATE OF REVISION OF THE TEXT

June 2015