

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Adalat LA 30 mg Prolonged-Release Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 30 mg nifedipine.

Each tablet contains 9.4mg sodium  
For a full list of excipients, see Section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release film-coated tablet

*Product imported from The Netherlands, Greece and Spain:*  
Pink, lacquered tablets printed 'Adalat 30' in black on one side, plain on the other 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

*Excipients present in product imported from The Netherlands and Spain:*

#### Tablet core

Polyethylene oxide  
Hypromellose  
Magnesium stearate

#### Osmotic Blend

Polyethylene oxide  
Sodium chloride  
Hypromellose  
Iron oxide red (E172)  
Magnesium stearate

#### Organic Coating

Cellulose acetate  
Macrogol

#### Light Protective Coating

Hyprolose  
Hypromellose  
Propylene glycol  
Titanium dioxide (E171)

Iron Oxide, red (E172)

Polish

Hypromellose

Printing ink

Iron oxide black (E172)

The printing ink for product imported from The Netherlands also includes shellac.

*Excipients present in the product imported from Greece:*

Polyethylene oxide

Hypromellose

Magnesium stearate

Sodium chloride

Iron oxide red (E172)

Cellulose acetate

Macrogol 4000

Propylene glycol

Titanium dioxide (E171)

## **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 25°C.

Store in the original package. The tablets should be protected from strong light.

## **6.5 Nature and contents of container**

Blister packs containing 28 tablets.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing

Unit 10, Ashbourne Business Park

Rath

Ashbourne

Co. Meath

Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/012/005

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14<sup>th</sup> December 2001

Date of last renewal: 14<sup>th</sup> December 2006

**10 DATE OF REVISION OF THE TEXT**

September 2014