

# 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 20mg nifedipine.

Excipient: Lactose monohydrate

*For a full list of excipients, see section 6.1.*

## 3 PHARMACEUTICAL FORM

- Film-coated, prolonged-release tablets

*Product imported from the UK:*

- Pink-grey circular tablets impressed with 'I U' on one face and the Bayer cross on the reverse.

*Product imported from Spain:*

- Pink-grey circular tablets with 'A 20' embossed on one face and the Bayer cross on the reverse.

## 4 CLINICAL PARTICULARS

As per PA 1410/025/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1410/025/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose (E460)

Polysorbate 80

Hypromellose

Lactose

Maize starch

Macrogol

Magnesium stearate

Titanium dioxide (E171)

Iron oxide (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be 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 container.

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

Blister packs of 56 or 60 tablets contained in an outer cardboard carton.

#### **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  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA 0465/012/003

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

Date of first authorisation: 12<sup>th</sup> August 1987

Date of last renewal: 12<sup>th</sup> August 2007

### **10 DATE OF REVISION OF THE TEXT**

Spetember 2016