

# 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 tablet.

*Product imported from Spain:*

Grey-pink circular tablets marked with 'A20' on one side and a 'Bayer cross' on the reverse.

*Product imported from Germany:*

Grey-pink, circular tablets marked with '1U' on one side and a '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

Polysorbate 80

Hypromellose

Lactose monohydrate

Maize starch

Macrogol 4000

Magnesium stearate

Titanium dioxide (E171)

Red 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**

Germany

Do not store above 25°C.

Store in the original package.

Spain

Store in the original package in order to protect from light.

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

Spain: Blister strips of tablets contained in an overlabelled cardboard outer carton. Pack size 60.

Germany: Blister strips of tablets in a reboxed carton. Pack size 56.

## **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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/047/001

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

Date of first authorisation: 7th March 2008

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

October 2017