

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Amlodipine 5 mg tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains amlodipine besilate equivalent to 5mg amlodipine.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from the UK:*

Round, white tablet. One side is slightly concave with a breakline and debossed "A5". The other side is slightly convex and plain.

The tablet can be divided into equal doses.

### 4 CLINICAL PARTICULARS

As per PA0749/067/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0749/067/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Microcrystalline cellulose  
Calcium hydrogen phosphate anhydrous  
Sodium starch glycolate  
Magnesium stearate

#### 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 in order to protect from light and moisture. Keep the blister in the outer carton.

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

Blister pack of 28 tablets contained in a carton.

## **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

WPR Healthcare Limited  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0565/059/001

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

Date of first authorisation: 31<sup>st</sup> July 2015

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