

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Amlodipine 10 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains amlodipine besilate equivalent to 10mg amlodipine.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:

Round, white, slightly concave with a breakline and debossed "A10" on one side. The other side is plain and slightly convex.

The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA0749/067/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/067/002

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

PPA0565/059/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st July 2015

10 DATE OF REVISION OF THE TEXT