

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Amlodipine 5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg of amlodipine (as amlodipine besilate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from The Netherlands
White coloured, round biconvex tablets debossed with “5” on one side and scored on other side.
The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA0577/133/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0577/133/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous calcium hydrogen phosphate
Cellulose, microcrystalline
Sodium starch glycolate (type A)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container of the product on the market in the country of origin.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Bottle with screw cap containing 500 tablets.

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/439/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2018

10 DATE OF REVISION OF THE TEXT