

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acercal 5mg/10mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 3.395 mg perindopril equivalent to 5 mg perindopril arginine and 13.870 mg amlodipine besilate equivalent to 10 mg amlodipine.

Excipient : lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Hungary and Poland:

White, square-shaped tablet engraved with 5/10 on one face and the Servier Company Logo on the other face.

4 CLINICAL PARTICULARS

As per PA 0568/018/002

5 PHARMACOLOGICAL PROPERTIES

As per PA 0568/018/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose, microcrystalline (E460)
Silica, colloidal anhydrous (E551)
Magnesium stearate (E470B)

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 and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Keep the container tightly closed in order to protect from moisture.

Store in the original package.

6.5 Nature and contents of container

30 tablets in polypropylene container equipped with a low density polyethylene flow reducer and a low density polyethylene stopper containing a desiccant gel.

Box of 1 container of 30 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/283/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 27th April 2012

10 DATE OF REVISION OF THE TEXT

April 2016