

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ACERYCAL 10mg/10mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 6.790 mg perindopril equivalent to 10 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 Poland:

White, round tablet engraved with 10/10 on one face and  on the other face.

4 CLINICAL PARTICULARS

As per PA0568/018/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0568/018/004

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 an overlabelled polypropylene container equipped with a low density polyethylene flow reducer and a low density polyethylene stopper containing a desiccant gel repackaged in an outer cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate,
Belvue Road,
Northolt,
Middlesex UB5 5QS,
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/035/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th January 2015.

10 DATE OF REVISION OF THE TEXT

October 2018