

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acerycal 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 equivalent to 10 mg amlodipine.


Excipient with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from Hungary:

White square shaped tablet engraved with 5/10 on one face and  on the other face.

4 CLINICAL PARTICULARS

As per PA0568/018/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0568/018/002

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 for 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

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/071/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2011

10 DATE OF REVISION OF THE TEXT

November 2017