Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lercaril 20 mg/10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 mg enalapril maleate (equivalent to 15.29 mg enalapril) and 10 mg lercanidipine hydrochloride (equivalent to 9.44 mg lercanidipine).

Excipient with known effect: Each tablet contains Lactose Monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Product imported from Spain
Yellow, circular, biconvex tablets of 8.5 mm.

4 CLINICAL PARTICULARS

As per PA1404/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1404/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose monohydrate,
microcrystalline cellulose
sodium starch glycolate (type A)
povidone K30
sodium bicarbonate
magnesium stearate
5 cp hypromellose
Titanium dioxide (E171)
Macrogol 6000
Talc
Aluminium lake quinoline yellow (E104)
Yellow Iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package 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 and moisture.
Do not store above 25°C.

6.5 Nature and contents of container

Blister packs of 28 tablets.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT