Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lercaril 20 mg/20 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 20 mg lercanidipine hydrochloride (equivalento to 18.88 mg lercanidipine).

Excipient(s) with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from France:
Orange, circular, biconvex tablets of 12 mm

4 CLINICAL PARTICULARS

As per PA1404/002/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1404/002/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Lactose monohydrate
Microcrystalline cellulose
Sodium starch glycolate
Povidone K30
Sodium hydrogen carbonate
Magnesium stearate

Film-Coating:
Hypromellose
Titanium dioxide (E171)
Macrogol 6000
Iron oxide yellow (E172)
Talc
Iron oxide red (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of 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

Polyamide-aluminium-PVC/aluminium blister.
Blisters containing 15 tablets.
Each pack contains 30 tablets.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/472/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th February 2023

10 DATE OF REVISION OF THE TEXT