Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lercaril 10 mg/10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg enalapril maleate (equivalent to 7.64 mg enalapril) and 10 mg lercanidipine hydrochloride (equivalent to 9.44 mg lercanidipine).

Excipients with known effect: Lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Spain
White, circular, biconvex tablets of 8.5 mm.

4 CLINICAL PARTICULARS

As per PA1404/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1404/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Lactose monohydrate
Cellulose microcrystalline
Sodium starch glycolate Type A
Povidone K30
Sodium hydrogen carbonate
Magnesium stearate

Film-Coating:
Hypromellose 5 cP
Titanium dioxide (E171)
Talc
Macrogol 6000

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

Blisters containing 28 tablets

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd,
Unit 625 Kilshane Avenue,
Northwest Business Park,
Ballycoolin,
Dublin 15,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/198/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th November 2022

10 DATE OF REVISION OF THE TEXT