

# 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(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 Romania:*

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

*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

Quinoline yellow aluminium lake (E104)

Iron oxide yellow (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**

Blisters containing 14 tablets.

Each pack contains 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**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/472/002

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14<sup>th</sup> April 2022

### **10 DATE OF REVISION OF THE TEXT**

April 2022