

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar Comp 50 mg/12.5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of losartan potassium and 12.5 mg hydrochlorothiazide (HCTZ) as the active ingredients.

Excipient(s) 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 Italy and Poland:*

Yellow oval-shaped, film-coated tablet marked '717' on one side and a single score line on the other.

*Product imported from the United Kingdom:*

Yellow oval-shaped, film-coated tablet marked '717' on one side and plain or scored on the other side.

The score line is not intended for breaking the tablet.

## 4 CLINICAL PARTICULARS

As per PA1286/001/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1286/001/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hydroxypropylcellulose (E463)

Hypromellose (E464)

Lactose monohydrate

Magnesium stearate (E572)

Microcrystalline cellulose (E460)

Pregelatinised maize starch

Titanium dioxide (E171)

Quinoline Yellow aluminium lake (E104)

Carnauba wax (E903)

Contains 4.24 mg (0.108 mmol) of potassium

### 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**

Do not store above 30 °C.

Store in the original package in order to protect from light and moisture.

### **6.5 Nature and contents of container**

Blister packs of 14 tablets in an outer carton. Pack size 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**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/109/001

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

Date of first authorisation: 9<sup>th</sup> January 2004

Date of last renewal: 9<sup>th</sup> January 2009

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

October 2019