# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar Comp 100 mg/12.5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide (HCTZ).

Excipient with known effect:
Each film-coated tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from France:*
White, oval film-coated tablets, imprinted with '745' on one side and plain on the other side.

## 4 CLINICAL PARTICULARS

As per PA23198/001/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23198/001/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hydroxypropyl cellulose (E463)
Hypromellose (E464)
Lactose monohydrate
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Pregelatinised maize starch
Titanium dioxide (E171)
Carnauba wax (E903)
'Cozaar' Comp 100 mg/12.5 mg also contains 8.48 mg (0.216 mEq) of potassium.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is 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

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**

PVC/PE/PVDC blisters with aluminium foil lidding in cartons containing 28 tablets.

**6.6 Special precautions for disposal and other handling**

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**

PPA0465/109/004

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

Date of first authorisation: 16th April 2021

**10 DATE OF REVISION OF THE TEXT**

June 2022