

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar Comp 100 mg/25 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100mg of losartan potassium and 25mg of hydrochlorothiazide (HCTZ) as the active ingredients.

Excipient(s) with known effect: Lactose Monohydrate

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated Tablet

*Product imported from Italy, Hungary and France:*

'Cozaar' Comp is supplied as oval, yellow, film-coated tablets with '747' on one side and plain on the other.

## 4 CLINICAL PARTICULARS

As per PA23198/001/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23198/001/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hydroxypropyl cellulose (E463)

Hypromellose (E464)

Lactose monohydrate

Magnesium stearate (E572)

Microcrystalline cellulose (E460)

Pregelatinised starch

Titanium dioxide (E171)

Quinoline yellow aluminium lake (E104)

Carnauba wax (E903)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is 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**

White, opaque PVC/PE/PVDC blisters containing 28 tablets with aluminium foil lidding.

**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**

PPA0465/109/002

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

Date of First Authorisation: 8th February 2008

**10 DATE OF REVISION OF THE TEXT**

June 2022