

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar 100 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cozaar 100 mg tablet contains 100 mg of losartan potassium.

Excipient with known effect:

Each film-coated tablet contains lactose (as monohydrate)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated Tablet

*Product imported from Poland:*

White, teardrop-shaped, film-coated tablet marked "960" on one side and plain on the other.

## 4 CLINICAL PARTICULARS

As per PA23198/002/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23198/002/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hyprolose (E463)

Hypromellose (E464)

Lactose Monohydrate

Magnesium Stearate (E572)

Microcrystalline cellulose (E460)

Pregelatinised Maize Starch

Titanium Dioxide (E171)

Carnauba wax (E903)

Contains 8.48mg (0.216mEq) 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 carton 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.

**6.5 Nature and contents of container**

White opaque PVC/PE/PVDC blisters with aluminium foil lidding in an overlabelled outer carton.

Pack of 28 tablets.

**6.6 Special precautions for disposal**

No special 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**

PPA1463/029/002

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

Date of first authorisation: 12<sup>th</sup> February 2010

**10 DATE OF REVISION OF THE TEXT**

September 2022