

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar 50mg Film-Coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cozaar 50 mg tablet contains 50 mg of losartan potassium.  
Each Cozaar 50 mg tablet contains 25.5 mg lactose monohydrate.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film Coated Tablet

*Product imported from the UK and Poland:*

White, oval film-coated tablet marked "952" on one side and scored on the other.  
The score line allows the tablet to be divided into equal halves.

## 4 CLINICAL PARTICULARS

As per PA1286/004/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1286/004/002

## 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 4.24mg (0.108mEq) 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 container 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 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**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

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

PPA1463/029/001

### **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**

April 2016