

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Cozaar 100mg Film-coated Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cozaar 100mg tablet contains 100 mg losartan potassium.

Each Cozaar 100mg tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Film-coated tablets.

*Product imported from the UK and Poland:*

White, teardrop-shaped tablet with '960' marked on one side and plain on the other.

### 4 CLINICAL PARTICULARS

As per PA1286/004/003

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1286/004/003

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Hyprolose (E463)

Hypromellose (E464)

Lactose Monohydrate

Magnesium stearate (E572)

Microcrystalline cellulose (E460)

Pregelatinised starch

Titanium dioxide (E171)

Carnauba wax

Contains potassium 8.48mg (0.216 mEq)

#### 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 with aluminium foil lidding.

Blister packs containing 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  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/106/002

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

Date of first authorisation: 8th February 2008

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

September 2015