

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar 100mg Film-Coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 91.6mg losartan as 100mg losartan potassium.

Excipients: Lactose monohydrate

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from the United Kingdom, Italy and the Czech Republic:*

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

## 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 maize starch  
Titanium dioxide (E171)  
Carnauba wax

### 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

Store in the original package in order to protect from light and moisture.

## **6.5 Nature and contents of container**

Cardboard outer containing blister strips. Pack size 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**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/005/002

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

Date of First Authorisation: 22nd February 2008

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

July 2015