

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar 50mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cozaar 50mg tablet contains 50mg of losartan potassium.

Each Cozaar 50mg tablet contains 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 tablets marked ‘952’ on one side and scored on the other.

## 4 CLINICAL PARTICULARS

As per PA 1286/004/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 1286/004/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose (E460)  
Lactose monohydrate  
Pregelatinized maize starch  
Magnesium stearate (E572)  
Hyprolose (E463)  
Hypromellose (E464)

Contains potassium 4.24mg (0.108mEq)

Also contains Carnauba wax (E903), Titanium dioxide (E171)

### 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**

Blisters in an overlabelled outer carton containing 28 tablets.

### **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Clear Pharmacy  
157-173 Roden Street  
Belfast BT12 5QA  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1596/003/001

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

Date of first authorisation: 1st October 2010

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

October 2014