# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cozaar 100mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg of losartan potassium (equivalent to 91.6mg losartan)
Excipients: also includes lactose monohydrate. Each Cozaar 100mg Tablet contains 51.0mg lactose.
For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Film-coated Tablet

*Product imported from UK, Poland, Spain, Italy and Austria:*

White, teardrop-shaped film-coated tablets 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 maize starch
Titanium dioxide (E171)
Carnauba wax (E903)

Each Cozaar 100mg tablet contains potassium 8.48mg (0.216 mEq).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product shall be 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 25°C. Store in the original package in order to protect from light and moisture. Do not open the blister pack until you are ready to take the medicine.

## 6.5 Nature and contents of container

Pack of 28 film-coated tablets in white opaque blisters with foil lidding.

## 6.6 Special precautions for disposal and other handling

No special requirements.

## 7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/081/002

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

Date of first authorisation: 19th June 2009

## 10 DATE OF REVISION OF THE TEXT

March 2015