

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 100mg of losartan potassium.

Each Cozaar 100mg 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, teardrop-shaped film-coated tablets marked '960' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA 1286/004/003

5 PHARMACOLOGICAL PROPERTIES

As per PA 1286/004/003

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 8.48mg (0.216mEq)

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

PPA 1596/3/2

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