Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cozaar 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg losartan potassium.

Excipient with known effect
Lactose (as monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the Netherlands, Spain, Poland.

White, oval-shaped, film-coated tablet marked '952' on one side and a single score line on the other.

4 CLINICAL PARTICULARS

As per PA23198/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

List of excipients
Hyprolose
Hypromellose
Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose
Pregelatinised starch
Titanium dioxide
Carnauba wax

COZAAR 50 mg film coated Tablets also contain 4.24 mg (0.108 mEq) potassium

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

Blisters of 28 or 30 film-coated tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/106/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2004

Date of last renewal: 6th February 2009

10 DATE OF REVISION OF THE TEXT

June 2022