

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 (equivalent to 45.8mg losartan).

Excipients: Lactose Monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Italy, UK and Spain:

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

4 CLINICAL PARTICULARS

As per PA1286/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/004/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Italy and the UK:

Hyprolose
Hypromellose
Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose
Pregelatinised starch
Titanium dioxide (E171)
Carnauba wax

Product imported from Spain:

Microcrystalline cellulose (E460)
Lactose monohydrate
Pregelatinised maize starch
Magnesium stearate (E572)
Hyprolose (E463)
Hypromellose (E464)
Carnauba wax (E903)
Titanium dioxide (E171)

'Cozaar' 50 mg also contains 4.24 mg (0.108mEq) of 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

Product imported from Italy and the UK:

Do not store above 30°C. Store in the original package in order to protect from light and moisture.

Product imported from Spain:

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

PPA1151/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th July 2004

Date of last renewal: 30th July 2009

10 DATE OF REVISION OF THE TEXT

October 2014