

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cozaar Comp 50 mg/12.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of losartan potassium and 12.5 mg hydrochlorothiazide (HCTZ) as the active ingredients.

Excipient(s) with known effect: Each tablet contains lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Italy and Poland:

Yellow oval-shaped, film-coated tablet marked '717' on one side and a single score line on the other.

The score line is not intended for breaking the tablet.

4 CLINICAL PARTICULARS

As per PA23198/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylcellulose (E463)

Hypromellose (E464)

Lactose monohydrate

Magnesium stearate (E572)

Microcrystalline cellulose (E460)

Pregelatinised maize starch

Titanium dioxide (E171)

Quinoline Yellow aluminium lake (E104)

Carnauba wax (E903)

Contains 4.24 mg (0.108 mmol) of potassium

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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 30 °C.

Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister packs of 14 tablets in an outer carton. 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/109/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th January 2004

Date of last renewal: 9th January 2009

10 DATE OF REVISION OF THE TEXT

July 2023