

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cozaar 100 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cozaar 100 mg tablet contains 100 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 Poland.

White, teardrop-shaped tablet with '960' marked on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA23198/002/003

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/002/003

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

Contains potassium 8.48 mg (0.216 mEq)

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

White opaque PVC/PE/PVDC blisters with aluminium foil lidding.

Blister packs of 28 tablets

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

PPA0465/106/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th February 2008

10 DATE OF REVISION OF THE TEXT

June 2022