Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cozaar Comp 100 mg/12.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide (HCTZ).

Excipient with known effect:
Each film-coated tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from France:
White, oval film-coated tablets, imprinted with '745' on one side and plain on the other side.

4 CLINICAL PARTICULARS

As per PA23198/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropyl cellulose (E463)
Hypromellose (E464)
Lactose monohydrate
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Pregelatinised maize starch
Titanium dioxide (E171)
Carnauba wax (E903)
'Cozaar' Comp 100 mg/12.5 mg also contains 8.48 mg (0.216 mEq) 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 blister 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

PVC/PE/PVDC blisters with aluminium foil lidding in cartons containing 28 tablets.

6.6 Special precautions for disposal and other handling

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

PPA0465/109/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th April 2021

10 DATE OF REVISION OF THE TEXT

June 2022