Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cozaar Comp 100 mg/25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100mg of losartan potassium and 25mg of hydrochlorothiazide (HCTZ) as the active ingredients.

Excipient(s) with known effect: Lactose Monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Italy, Hungary and France:
'Cozaar' Comp is supplied as oval, yellow, film-coated tablets with '747' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA23198/001/003

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/001/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropyl cellulose (E463)
Hypromellose (E464)
Lactose monohydrate
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Pregelatinised starch
Titanium dioxide (E171)
Quinoline yellow aluminium lake (E104)
Carnauba wax (E903)

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 containing 28 tablets with aluminium foil lidding.

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

PPA0465/109/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 8th February 2008

10 DATE OF REVISION OF THE TEXT

July 2023