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 tablet contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide (HCTZ).

Excipients with known effect:
lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

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

4 CLINICAL PARTICULARS

As per PA23198/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

microcrystalline cellulose (E460)
lactose monohydrate
pregelatinised maize starch
magnesium stearate (E572)
hydroxypropyl cellulose (E463)
hypromellose (E464)
titanium dioxide (E171)
carnauba wax (E903)
'Cozaar' Comp 100 mg/12.5 mg 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 blister with aluminium foil lidding in cartons containing 28 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd,
Unit 625 Kilshane Avenue,
Northwest Business Park,
Ballycoolin,
Dublin 15,
Ireland.

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/225/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th July 2024

10 DATE OF REVISION OF THE TEXT