Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cozaar 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cozaar 50 mg tablet contains 50 mg of losartan potassium.

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Poland:
White, oval film-coated tablet marked "952" on one side and scored on the other.
The score line is not intended for breaking the tablet.

4 CLINICAL PARTICULARS

As per PA23198/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hyprolose (E463)
Hypromellose (E464)
Lactose Monohydrate
Magnesium Stearate (E572)
Microcrystalline cellulose (E460)
Pregelatinised Maize Starch
Titanium Dioxide (E171)
Carnauba wax (E903)
Contains 4.24mg (0.108mEq) 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 carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Store in the original container 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 in an overlabelled outer carton.

Pack of 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

PPA1463/029/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th February 2010

10 DATE OF REVISION OF THE TEXT

September 2022