

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Co-Diovan 80 mg/12.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 80 mg of valsartan and 12.5 mg of hydrochlorothiazide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Italy:

Light orange, ovaloid tablet imprinted with 'HGH' on one side and 'CG' on the other side.

4 CLINICAL PARTICULARS

As per PA0896/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tabletcore:

Microcrystalline cellulose

Colloidal anhydrous silica

Crospovidone

Magnesium stearate

Coating:

Hypromellose

Macrogol 8000

Talc

Red iron oxide (E172)

Yellow iron oxide (E172)

Titanium dioxide (E171)

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 carton of the product as marketed 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 moisture.

6.5 Nature and contents of container

Foil blisters in a cardboard carton 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

PPA1463/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st January 2011

10 DATE OF REVISION OF THE TEXT

January 2021