# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Co-Diovan 160 mg/25 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 160 mg of valsartan and 25 mg of hydrochlorothiazide.
For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated Tablet

*Product imported from Italy:*
Brown, ovaloid tablets, imprinted with “HXH” on one side and “NVR” on the other side.

## 4 CLINICAL PARTICULARS

As per PA0896/007/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0896/007/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Tablet core:*
Microcrystalline cellulose
Silica, colloidal anhydrous
Crospovidone
Magnesium stearate

*Coating:*
Hypromellose
Macrogol 4000
Talc
Titanium dioxide (E171)
Red iron oxide (E172)
Yellow iron oxide (E172)
Black iron oxide (E172)

### 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 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 moisture.

**6.5 Nature and contents of container**

Foil blisters in a cardboard carton containing 28 tablets.

**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 MARKETING AUTHORISATION HOLDER**

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

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**8 MARKETING AUTHORISATION NUMBER**

PPA1463/043/003

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/043/003

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 16th September 2011.

**10 DATE OF REVISION OF THE TEXT**

December 2019