

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Co-Diovan 160 mg/12.5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 160 mg of valsartan and 12.5 mg of hydrochlorothiazide.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Italy:*

Dark red, ovaloid tablet imprinted with "HHH" on one side and "CG" on the other side.

## 4 CLINICAL PARTICULARS

As per PA0896/007/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0896/007/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core:

Microcrystalline cellulose  
Colloidal anhydrous silica  
Crospovidone  
Magnesium stearate

Coating:

Hypromellose  
Macrogol 8000  
Talc  
Titanium dioxide (E171)  
Red 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 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 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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Unit 625 Kilshane Avenue  
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Dublin 15  
Ireland

### **8 MARKETING AUTHORISATION NUMBER**

PPA1463/043/002

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/043/002

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

Date of first authorisation: 21<sup>st</sup> January 2011

### **10 DATE OF REVISION OF THE TEXT**

December 2019