

# 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 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 the UK and 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

#### Tablet core:

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 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 moisture.

#### **6.5 Nature and contents of container**

28 film-coated tablets contained in blister packs in an outer carton.

#### **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 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

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

PPA0465/226/001

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

Date of first authorisation: 31<sup>st</sup> July 2009

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

March 2019

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