

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Diovan 160 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 160 mg valsartan.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Italy:*

Grey-orange, ovaloid film-coated tablet, slightly convex, scored on one side with debossing "DX" on one side of the score and "DX" on the other side of the score and "NVR" on the reverse side of the tablet. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4 CLINICAL PARTICULARS

As per PA0896/009/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0896/009/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core:

Microcrystalline cellulose  
Crospovidone Type A  
Colloidal anhydrous silica  
Magnesium stearate

Film coat:

Hypromellose  
Titanium dioxide (E171)  
Macrogol 8000  
Iron oxide red (E172)  
Iron oxide black (E172)  
Iron oxide yellow (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 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**

Blisters containing 28 film-coated tablets contained in an outer cardboard 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**

PPA0465/461/001

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

Date of first authorisation: 21<sup>st</sup> May 2021

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