

# 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 Spain, Poland and the Netherlands*

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 scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4 CLINICAL PARTICULARS

As per PA0013/079/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0013/079/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Tablet core

Microcrystalline cellulose  
Crospovidone  
Colloidal anhydrous silica  
Magnesium stearate

#### Film coat

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

Blister packs 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  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/180/002

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

Date of first authorisation: 31<sup>st</sup> August 2012

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

February 2018