

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diovan 80 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 80 mg valsartan.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Belgium, Spain, Poland and the Netherlands

Pale red, round, film-coated tablet with bevelled edges, scored on one side, with debossing “D” on one side of the score and “V” 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 PA0013/079/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/079/003

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)

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 or 56 film-coated tablets contained in an outer cardboard carton.

Not all pack sizes may be marketed.

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

PPA0465/180/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 2006

Date of last renewal: 01 September 2011

10 DATE OF REVISION OF THE TEXT

February 2018