Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Co-Diovan 160 mg/25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 160 mg of valsartan and 25 mg hydrochlorothiazide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK and Italy
Brown, ovaloid tablet imprinted with "HXH" on one side and "NVR" on the other side.

4 CLINICAL PARTICULARS

As per PA0896/007/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/007/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Microcrystalline cellulose
Colloidal anhydrous silica
Crospovidone
Magnesium stearate

Coating:
Hypromellose
Macrogol 8000 or macrogol 4000
Talc
Red iron oxide (E172)
Yellow iron oxide (E172)
Black 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

PPA0465/226/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st July 2009

10 DATE OF REVISION OF THE TEXT

March 2019

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