

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Co-Diovan 320 mg/12.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 320 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 Italy:

Pink, ovaloid shaped, beveled edge tablets, imprinted with "NVR" on one side and "HIL" on the other side.

4 CLINICAL PARTICULARS

As per PA0896/007/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/007/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Microcrystalline cellulose
Silica, Colloidal anhydrous
Crospovidone
Magnesium stearate

Coating:

Hypromellose
Macrogol 4000
Talc
Titanium dioxide (E171)
Black iron oxide (E172)
Red iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the blister and on the outer carton.

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: 28 (calendar pack) film-coated tablets in a 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

PPA0465/226/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th April 2013

10 DATE OF REVISION OF THE TEXT

March 2019

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