

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Co-Diovan 320 mg/25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 320 mg valsartan and 25 mg hydrochlorothiazide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Italy:

Yellow, ovaloid shaped, beveled edge, film coated tablet, imprinted (debossed) with "NVR" on one side and "CTI" on the reverse side.

4 CLINICAL PARTICULARS

As per PA0896/007/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/007/005

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)
Yellow iron oxide (E172)

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

Store in the original package in order to protect from moisture.

Do not store above 30 °C

6.5 Nature and contents of container

28 film-coated tablets contained in blisterpacks 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

PPA0465/226/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th November 2012

10 DATE OF REVISION OF THE TEXT

March 2019

CRN008WLC