

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Co-Diovan 80mg/12.5mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 80mg of valsartan and 12.5mg of hydrochlorothiazide.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated Tablet

Product imported from Italy

Light orange, ovaloid tablet imprinted with “HGH” on one side and “CG” on the other side.

4 CLINICAL PARTICULARS

As per PA0013/091/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/091/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Microcrystalline cellulose
Colloidal anhydrous silica
Crospovidone
Magnesium stearate

Coating:

Hypromellose
Macrogol 8000
Talc
Titanium dioxide (E171)
Red iron oxide (E172)
Yellow 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 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

The tablets are supplied in blister pack of 28 tablets.

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

B&S Healthcare
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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/178/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th January 2013

10 DATE OF REVISION OF THE TEXT

January 2016