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 film-coated tablet contains 160 mg of valsartan and 25 mg of hydrochlorothiazide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from 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
Silica, Colloidal anhydrous
Crospovidone
Magnesium stearate

Coating:
Hypromellose
Macrogol 4000
Talc
Titanium dioxide (E171)
Red iron oxide (E172)
Yellow iron oxide (E172)
Black iron oxide (E172).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be 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 blisters marked with the days of the week in an outer carton.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3, Harcourt Centre,
Harcourt Road,
Dublin 2,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/046/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th June 2022

10 DATE OF REVISION OF THE TEXT