

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diovan 160 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 160 mg valsartan.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from Italy:

Grey-orange, ovaloid film-coated tablet, slightly convex, scored on one side with debossing "DX" on one side of the score and "DX" on the other side of the score and "NVR" on the reverse side of the tablet.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0896/009/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/009/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core

Microcrystalline cellulose

Crospovidone

Colloidal anhydrous silica

Magnesium stearate

Film coat

Hypromellose

Titanium dioxide (E171)

Macrogol 8000

Iron oxide red (E172)

Iron oxide yellow (E172)

Iron oxide black (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Cardboard carton containing blister strips. Each blister strip contains 14 tablets. Pack size 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/077/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th March 2013

10 DATE OF REVISION OF THE TEXT

February 2021