

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diovan 40mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 40mg valsartan.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from the UK:

Yellow, ovaloid film-coated tablet with beveled edges, slightly convex, scored on one side with debossing 'D' on one side of the score and 'O' on the other side of the score and 'NVR' on the reverse side of the tablet.

The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0013/079/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/079/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Microcrystalline cellulose
Crospovidone Type A
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 bottle and out carton of the product as marketed 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

Blister strips of 7 tablets in an outer cardboard carton.
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

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/067/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th May 2012

10 DATE OF REVISION OF THE TEXT

September 2014