Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diovan 80mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 80mg valsartan.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-Coated Tablet

Product imported from Spain, Poland and the Netherlands
Pale red, round, scored on one side, slightly convex, with bevelled edges, debossed on one side with D/V and NVR on the other side.

The score line allows the tablet to be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0013/079/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/079/003

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
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

Spain, Netherlands:

Cardboard outer containing blister strips. Pack size 28.

Poland:

Cardboard outer 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

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/067/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 3rd October 2008

10 DATE OF REVISION OF THE TEXT

October 2014