Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omesar 10mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20mg olmesartan medoxomil.
Excipient of known effect: lactose monohydrate - see leaflet for further information.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from Greece:
White, circular, film-coated tablets with ‘C13’ embossed on one side.

4 CLINICAL PARTICULARS

As per PA0865/011/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/011/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Microcrystalline cellulose
Lactose monohydrate
Hydroxypropylcellulose
Low substituted hydroxypropyl cellulose
Magnesium stearate

Tablet coating:
Titanium dioxide (E 171)
Talc
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister strips and outer carton of the product as marked in the country of origin.

6.4 Special precautions for storage

No special storage conditions.

6.5 Nature and contents of container

Cardboard outer carton containing blister strips.
Pack size: 28 film-coated 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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/154/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th May 2015

10 DATE OF REVISION OF THE TEXT