Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omesar 40mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Olmesartan medoxomil

Each film-coated tablet contains 40 mg of olmesartan medoxomil

Excipient with known effect: each film-coated tablet contains lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Greece and Italy:
White, oval, film-coated tablets with ‘C15’ embossed on one side.

4 CLINICAL PARTICULARS

As per PA 865/11/3

5 PHARMACOLOGICAL PROPERTIES

As per PA 865/11/3

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Cellulose, microcrystalline
Lactose monohydrate
Hydroxypropylcellulose
Low substituted hydroxypropylcellulose
Magnesium stearate

Tablet coat:
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 container and outer package of the product as marketed in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs of 28 film-coated tablets.

6.6 Special precautions for disposal

No special 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

PPA1463/047/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th August 2011.

10 DATE OF REVISION OF THE TEXT

November 2014