Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omesar 40 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Olmesartan medoxomil

Each tablet contains 40 mg of olmesartan medoxomil

Excipient with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablets.

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

4 CLINICAL PARTICULARS

As per PA0865/011/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/011/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline
Lactose monohydrate
Hydroxypropylcellulose
Low substituted hydroxypropylcellulose
Magnesium stearate
Titanium dioxide (E171)
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 pack and the outer package of the product on the market 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 or 30 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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/263/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2011

10 DATE OF REVISION OF THE TEXT

December 2016