Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omesar Plus 20 mg/12.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.

Excipient with known effect:
Lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Portugal, the UK and Greece:
Reddish-yellow, round, film-coated tablet with C22 debossed on one side.

4 CLINICAL PARTICULARS

As per PA0865/014/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/014/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Lactose monohydrate
Low substituted hyprolose
Hyprolose
Magnesium stearate
Talc
Hypromellose
Titanium dioxide (E 171)
Iron (III) oxides (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 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

Laminated polyamide/ aluminium/ polyvinyl chloride/ aluminium blisters in packs of 28 film-coated tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/273/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th August 2011

10 DATE OF REVISION OF THE TEXT

January 2020