Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omesar 20 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Olmesartan medoxomil
Each film-coated tablet contains 20 mg olmesartan medoxomil.

Excipient with known effect:
Lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK, Portugal and Greece:
White circular film-coated tablet with 'C14' embossed on one side of tablet.

4 CLINICAL PARTICULARS

As per PA0865/011/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/011/002

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

Laminated polyamide/aluminium/polyvinyl chloride/aluminium blister pack.

Packs of 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/263/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2011

10 DATE OF REVISION OF THE TEXT

May 2021