Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omesar 40 mg film-coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Olmesartan medoxomil.

Each film-coated tablet contains 40 mg 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 tablets.

Product imported from Italy:
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

Microcrystalline cellulose
Lactose monohydrate
Hydroxypropylcellulose
Low substituted hydroxypropylcellulose
Magnesium stearate
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 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 // aluminiumblister pack.

Pack 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

6.6 Special precautions for disposal

No special requirements**.**

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch, Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/140/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th January 2015.

10 DATE OF REVISION OF THE TEXT

September 2018