

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Omesar Plus 20mg/12.5mg film-coated tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) 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 Greece*

Reddish-yellow, round, film-coated tablets of 8.5mm 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

Tablet core

Microcrystalline cellulose,

Lactose monohydrate,

Low substituted hypolose,

Hypolose,

Magnesium stearate,

Tablet coating

Titanium dioxide (E171)

Talc

Hypromellose

Iron (III) oxides (E172)

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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**

Packs of 28 film-coated tablets.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon (UK) Ltd  
Unit 18  
Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire  
B98 0RE  
United Kingdom

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1097/006/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 13<sup>th</sup> April 2017

### **10 DATE OF REVISION OF THE TEXT**