

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Omesar 10 mg film-coated tablets.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Olmesartan medoxomil.

Each film-coated tablet contains 10 mg 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 Greece:*

White, circular, film-coated tablets with C13 embossed on one side.

### 4 CLINICAL PARTICULARS

As per PA0865/011/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0865/011/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

*Tablet core*

Cellulose, microcrystalline

Lactose monohydrate

Hydroxypropylcellulose

Low substituted hydroxypropylcellulose

Magnesium stearate

*Tablet coat*

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**

Blister 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**

IMED Healthcare Ltd  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/047/003

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

Date of first authorisation: 24<sup>th</sup> November 2014

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