

## 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.

Excipients with known effect: each film-coated tablet contains lactose monohydrate

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Film-coated tablets.

*Product imported from Greece and the UK:*

White, circular, film-coated tablets with C14 embossed on one side.

### 4 CLINICAL PARTICULARS

As per PA0865/011/002.

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0865/011/002.

### 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 is 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**

Blister packs of 28 film-coated tablets in an overlabeled carton.

#### **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**

PPA 1463/047/002

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

Date of first authorisation: 7<sup>th</sup> October 2011

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

March 2015