

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Konverge 40mg/10mg film-coated tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Konverge 40 mg/10 mg film-coated tablets:

Each film-coated tablet of Konverge contains 40 mg of olmesartan medoxomil and 10mg of amlodipine (as amlodipine besilate).

For the full list of excipients see section 6.1.

### 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Greece*

Brownish-red, round, film-coated tablet of 8mm with C77 debossed on one side.

### 4 CLINICAL PARTICULARS

As per PA0865/017/003

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0865/017/003

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Tablet core:

Starch, pregelatinised maize

Silicified microcrystalline cellulose

Croscarmellose sodium

Magnesium stearate

Tablet coat:

Polyvinyl alcohol

Macrogol 3350

Talc

Titanium dioxide (E171)

Iron (III) oxide yellow (E172)

Iron (III) oxide red (E172)

#### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf-life expiry date of this product is the date shown on the container and outer carton 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**

Aluminium / PVC / Aluminium blister.

Pack sizes: 28 film-coated tablets.

### **6.6 Special precautions for disposal and other handling**

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**

PPA1463/104/003

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

Date of first authorisation: 4th December 2015

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