

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Konverge 20mg/5mg film-coated tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Konverge 20 mg/5 mg film-coated tablets:

Each film-coated tablet of Konverge contains 20 mg of olmesartan medoxomil and 5 mg 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*

White, round, film-coated tablet of 6mm with C73 debossed on one side.

### 4 CLINICAL PARTICULARS

As per PA0865/017/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0865/017/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Tablet core:

Starch, pregelatinised maize

Silicified microcrystalline cellulose (microcrystalline cellulose with colloidal silicon dioxide)

Croscarmellose sodium

Magnesium Stearate

Tablet coat:

Polyvinyl alcohol

Macrogol 3350

Talc

Titanium dioxide (E171)

#### 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**

Blister strips of tablets in a cardboard outer container, in packs of 28 film-coated tablets.

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

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**

PPA1562/175/001

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

Date of first authorisation: 16<sup>th</sup> September 2016

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

July 2018