

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Coversyl Arginine Plus 5mg/1.25mg Film-coated Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 3.395 mg perindopril corresponding to 5 mg perindopril arginine and 1.25 mg indapamide.

Excipient: lactose monohydrate

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Film-coated Tablets

*Product imported from UK:*

White, rod-shaped film-coated tablets

### 4 CLINICAL PARTICULARS

As per PA0568/016/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0568/016/002

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

*Core:*

Lactose monohydrate

Magnesium stearate (E470B)

Maltodextrin

Silica colloidal anhydrous (E551)

Sodium starch glycolate (type A)

*Film Coating:*

Glycerol (E422)

Hypromellose (E464)

Macrogol 6000

Magnesium stearate (E470B)

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 container and outer package of the product on the market in the country of origin.

### **6.4 Special precautions for storage**

Keep the container tightly closed in order to protect from moisture.

### **6.5 Nature and contents of container**

30 tablets in polypropylene white container equipped with a low density polyethylene flow reducer and a low density polyethylene white opaque stopper containing a white desiccant gel.

Pack size: 1 x 30

### **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**

LTT Pharma Limited  
Unit 18  
Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire  
B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/063/001

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

Date of first authorisation: 4<sup>th</sup> November 2011

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

September 2016