

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Coversyl Arginine 5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Perindopril arginine.

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

Excipient with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Greece, Poland, Hungary and the UK:*

Light-green, rod-shaped film-coated tablet engraved with the Servier logo on one face and scored on both edges.

The tablet can be divided into equal halves.

## 4 CLINICAL PARTICULARS

As per PA0568/002/005

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0568/002/005

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Core:*

Lactose monohydrate

Magnesium stearate

Maltodextrin

Hydrophobic colloidal silica

Sodium starch glycolate (type A)

*Film-coating:*

Glycerol (E422a)

Hypromellose (E464)

Copper chlorophyllin (E141 ii)

Macrogol

Magnesium stearate

Titanium dioxide (E171)

### 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**

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

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

*Product imported from Greece, UK & Poland:*

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

*Product imported from Hungary:*

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

### **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/067/004

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

Date of first authorisation: 31st August 2007

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

January 2020