

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Acerycal 5 mg/10 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 3.395 mg perindopril equivalent to 5 mg perindopril arginine and 13.870 mg amlodipine besilate equivalent to 10 mg amlodipine

Excipient : lactose monohydrate.

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Hungary and Poland:*

White, square-shaped tablet engraved with 5/10 on one face and the Servier Company Logo on the other face.

## 4 CLINICAL PARTICULARS

As per PA0568/018/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0568/018/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate

Cellulose, microcrystalline (E460)

Silica, colloidal anhydrous (E551)

Magnesium stearate (E470B)

### 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**

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

Store in the original package.

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

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

Box of 1 container of 30 tablets.

#### **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**

PPA0465/283/003

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

Date of First Authorisation: 27th April 2012

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

November 2021