

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Atacand 16 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 16 mg candesartan cilexetil.  
Each tablet also contains Lactose Monohydrate

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Italy:*  
Pink, round tablets with a score and marked ‘A/CH’ on one side and ‘016’ on the other side.

*Product imported from the UK and Italy:*  
Light pink tablets with one convex side and one scored flat side, embossed ‘16’ on the convex side.

## 4 CLINICAL PARTICULARS

As per PA0970/030/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0970/030/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carmellose calcium  
Hyprolose  
Lactose monohydrate  
Magnesium stearate  
Maize starch  
Macrogol  
Iron 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 package of the product on the market in the country of origin.

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

Do not store above 30°C.

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

Blister pack containing 28 tablets.

#### **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**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/116/002

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

Date of first authorizations: 6<sup>th</sup> February 2004

Date of last renewal: 6<sup>th</sup> February 2009

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

January 2015