

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Atacand 4mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4mg candesartan cilexetil.

Excipient(s) with known effect: lactose

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from the Netherlands:*

White, round tablets with a scoreline and marked 'A/CF' on one side and '004' on the other.

*Product imported from the UK:*

White, round tablets with a single score line on both sides.

## 4 CLINICAL PARTICULARS

As per PA0970/030/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0970/030/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carmellose calcium

Hyprolose

Lactose monohydrate

Maize starch

Macrogol

Magnesium stearate

### 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 15 or 28 tablets.  
Not all pack sizes may be marketed

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

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/116/003

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

Date of first authorisation: 04 November 2005  
Date of last renewal: 04 November 2010

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

January 2015