

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Atacand Plus 16 mg/12.5 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One Atacand Plus 16 mg/12.5 mg tablet contains 16 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide.

### Excipient(s) with known effect:

Lactose Monohydrate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

### *Product imported from the Netherlands*

Peach, oval, biconvex tablets marked 'A/CS' on one side and scored on both sides.

### *Product imported from Italy*

Peach, oval, biconvex tablets marked A/CS on one side and scored on both sides or Pink, oval tablets marked 16/C and scored on both sides.

## 4 CLINICAL PARTICULARS

As per PA1019/005/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/005/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carmellose calcium  
Hyprolose  
Lactose monohydrate  
Magnesium stearate  
Maize starch  
Macrogol  
Iron Oxide (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton 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**

Product imported from Italy presented as 28 tablets in a blister pack contained in an outer cardboard carton.  
Product imported from The Netherlands presented as 30 tablets in a blister pack contained in an overlabelled outer carton.  
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 Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

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

PPA0465/117/001

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

Date of first authorisation: 26<sup>th</sup> January 2004

Date of last renewal: 26<sup>th</sup> January 2009

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

May 2019