

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Atacand 16mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 16 mg candesartan cilexetil.

Excipient with known effect: lactose monohydrate.  
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablets.

*Product imported from Italy & UK*

Atacand 16mg imported from Italy are round, pink tablets with a score and marked A/CH on one side and marked 016 on the other side.

The tablets can be divided into equal halves.

Atacand 16mg imported from UK are light pink, round tablets with one convex side embossed '16' and one flat side with a score line.

## 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  
Hydroxypropyl cellulose  
Iron oxide red E172  
Lactose monohydrate  
Magnesium stearate  
Maize starch  
Macrogol

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

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

Do not store above 30°C.

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

Cardboard outer containing blister strips.  
Pack size: 28

#### **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**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9.

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

PPA1151/109/001

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

Date of first authorisation: 19<sup>th</sup> June 2009

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

February 2015