

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Atacand 8 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8 mg candesartan cilexetil.

Excipient:

Each 8 mg tablet contains 89.4 mg lactose monohydrate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablets.

*Product imported from UK*

Round, light pink tablets with a scoreline on each side.

## 4 CLINICAL PARTICULARS

As per PA1019/004/002.

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/004/002.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carmellose calcium  
Hydroxypropyl cellulose  
Iron oxide (E 172)  
Lactose monohydrate  
Magnesium stearate  
Maize starch  
Macrogol

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be 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 carton containing blister strips. Pack size 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**

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

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

PPA1151/109/003

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

Date of first authorisation: 12th October 2012

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

July 2019