

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Atacand 8mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8mg candesartan cilexetil.

Excipients: Contains lactose monohydrate

For a full list of excipients, see 6.1

## 3 PHARMACEUTICAL FORM

Tablets

*Product imported from the UK:*

Round, pale pink tablets with a single score line on both sides.

*Product imported from Italy:*

Round, light pink tablets with a score and marked A/CG on one side and 008 on the other side.

## 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  
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 strip and outer package of the product in the country of origin

### 6.4 Special precautions for storage

Do not store above 30°C

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

### UK product

Cardboard carton containing 4 polypropylene blister strips (7 tablets per strip).  
Pack size 28 tablets.

### Italian product

Over-labelled cardboard carton containing 2 blister strips (14 tablets per strip).  
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**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/031/001

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

Date of first authorisation: 5<sup>th</sup> February 2010

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

November 2014