Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atacand 16 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 16 mg candesartan cilexetil.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets

Product imported from Italy:
Round, light pink tablets with a score and marked A/CH on one side and 016 on the other side.

The tablet can be divided in equal doses.

4 CLINICAL PARTICULARS

As per PA2239/010/003

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/010/003

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

Over-labelled cardboard carton containing 2 blister strips (14 tablets per strip).
Pack size 28 tablets.

6.6 Special precautions for disposal and other handling

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

PPA1463/031/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th February 2010

10 DATE OF REVISION OF THE TEXT

February 2022