Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atacand Plus 16mg/12.5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Each tablet contains lactose monohydrate.

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Italy:
Peach, oval, biconvex tablets with a score on both sides and engraved A/CS on one side,

or

Pink, oval tablets marked 16/C and scored on both sides.

4 CLINICAL PARTICULARS

As per PA0970/031/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/031/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose calcium
Hydroxypropylcellulose
Iron oxide (E172)
Lactose monohydrate
Magnesium stearate
Maize starch
Macrogol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this pack shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

6.5 Nature and contents of container

16/12.5 mg tablet: PVC/PVDC blister packs of 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/053/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th October 2011

10 DATE OF REVISION OF THE TEXT

October 2019