Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atacand Plus 16 mg/12.5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 16 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide.

Excipient with known effect
Lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Italy
Pink, oval tablets marked 16/C and scored on both sides.

4 CLINICAL PARTICULARS

As per PA2239/011/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/011/002

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

Blisters of 28 tablets.

6.6 Special precautions for disposal

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

March 2021