Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atacand Plus 16 mg/12.5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the Netherlands:
Peach, oval, biconvex tablets marked 'A/CS' on one side and scored on both sides.

Product imported from Italy:
Peach, oval, biconvex tablets marked A/CS on one side and scored on both sides or 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
Hyprolose
Lactose monohydrate
Magnesium stearate
Maize starch
Macrogol
Iron Oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

Product imported from Italy presented as 28 tablets in a blister pack contained in an outer cardboard carton.
Product imported from The Netherlands presented as 30 tablets in a blister pack contained in an overlabelled outer carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/117/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 2004
Date of last renewal: March 2019

10 DATE OF REVISION OF THE TEXT

April 2025