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: Lactose.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Product imported from Greece:
Pink, round tablets with a scoreline and marked ‘A/CH’ on one side and marked ‘016’ on the other side.

Product imported from the UK:
Pink, round tablets with one convex side embossed '16' and one flat side with a scoreline.

4 CLINICAL PARTICULARS

As per PA0970/030/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/030/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose calcium
Hydroxypropyl cellulose
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 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

Do not store above 30°C.

6.5 Nature and contents of container

PVC/PVDC blister packs of 14 and 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

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/018/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th October 2006

Date of last renewal: 6th October 2011

10 DATE OF REVISION OF THE TEXT

May 2015