

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

Tablet.

Product imported from Italy, Portugal and Poland:

Pink, round tablets with a score and marked 'A/CH' on one side and '016' on the other side.

Product imported from Italy:

Light pink tablets with one convex side and one scored flat side, embossed '16' on the convex side.

The tablet can be divided into 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

The product imported from Italy contains:

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

The product imported from Portugal and Poland contains:

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 is 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

Blister pack containing 28 tablets.

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

PPA0465/116/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2004

Date of last renewal: 6th February 2009

10 DATE OF REVISION OF THE TEXT

September 2022