

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atacand 8 mg tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8 mg candesartan cilexetil.

Excipient:
Each 8 mg tablet contains 89.4 mg lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.
Product imported from UK
Round, light pink tablets with a scoreline on each side.

4 CLINICAL PARTICULARS

As per PA0970/030/003.

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/030/003.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose calcium
Hydroxypropyl cellulose
Iron oxide (E 172)
Lactose monohydrate
Magnesium stearate
Maize starch
Macrogol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Cardboard outer carton containing blister strips. Pack size 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

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/109/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th October 2012

10 DATE OF REVISION OF THE TEXT

February 2015