Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cozaar Comp 100mg/25mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100mg Losartan potassium (equivalent to 91.6mg of losartan) and 25mg Hydrochlorthiazide

Each tablet contains 126.26mg lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet.

Product imported from the UK and Italy:
Oval, yellow, film-coated tablets with '747' on one side and plain on the other

4 CLINICAL PARTICULARS

As per PA 1286/001/003

5 PHARMACOLOGICAL PROPERTIES

As per PA 1286/001/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hyprolose (E463)
Hypromellose (E464)
Lactose monohydrate
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Pregelatinised maize starch
Titanium dioxide (E171)
Quinoline Yellow Aluminium Lake (E104)
Carnuba Wax (E903)

Cozaar Comp 100mg/25mg contains 8.48mg (0.216mEq) of potassium.

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^{o}C. Store in the original package. Do not open the blister pack until you are ready to take the medicine.

6.5 Nature and contents of container

White opaque blister with foil lidding.
Pack of 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

PPA1328/091/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd July 2009

10 DATE OF REVISION OF THE TEXT

November 2014