

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Coversyl Arginine 10mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

6.790 mg perindoprilcorresponding to 10 mg perindopril arginine.

Excipients: Also includes lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK and Poland:

Green, round, biconvex, film-coated tablet engraved with Servier logo on one face and heart on the other face.

4 CLINICAL PARTICULARS

As per PA0568/002/006

5 PHARMACOLOGICAL PROPERTIES

As per PA0568/002/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Lactose monohydrate

Magnesium stearate (E470B)

Maltodextrin

Hydrophobic colloidal silica

Sodium starch glycolate (type A)

Film-coating:

Glycerol (E422a)

Hypromellose (E464)

Copper chlorophyllin (E141(ii))

Macrogol

Magnesium stearate (E470B)

Titanium dioxide (E171)

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

Keep the container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Tablets are available in a white bottle equipped with a flow reducer and a white opaque stopper containing a desiccant gel. Each pack contains 30 film-coated tablets.

6.6 Special precautions for disposal and other handling

Medicines no longer required should not be disposed of via the waste water or the municipal sewage system. Return them to a pharmacy or ask your pharmacist how to dispose of them in accordance with the national regulations. These measures will help to protect the environment.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/080/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 8th April 2009

10 DATE OF REVISION OF THE TEXT

October 2014