

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Coversyl Arginine 5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Perindopril arginine.

One film-coated tablet contains 3.395 mg perindopril corresponding to 5 mg perindopril arginine.

Excipient: lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Hungary and Poland:

Light-green, rod-shaped film-coated tablet engraved with [Servier logo] on one face and scored on both edges. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0568/002/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0568/002/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Magnesium stearate
Maltodextrin
Hydrophobic colloidal silica
Sodium starch glycolate (type A)
Glycerol
Hypromellose
Copper chlorophyllin
Macrogol
Titanium dioxide

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 carton 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

30 tablets in a white tablet container equipped with a flow reducer and a white or green opaque stopper in an overlabelled cardboard box.

Box of 1 container of 30 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

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

Clear Pharmacy
157-173 Roden Street
Belfast BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th November 2010

10 DATE OF REVISION OF THE TEXT

June 2017