

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Coversyl Arginine Plus 5mg/ 1.25mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 3.395 mg perindopril corresponding to 5 mg perindopril arginine and 1.25 mg indapamide.

Excipient : lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK & Hungary:
White, rod-shaped film-coated tablet.

4 CLINICAL PARTICULARS

As per PA 0568/016/002

5 PHARMACOLOGICAL PROPERTIES

As per PA 0568/016/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Lactose monohydrate
Magnesium stearate
Maltodextrin
Silica colloidal anhydrous
Sodium starch glycolate (type A)

Film-coating:
Glycerol
Hypromellose
Macrogol 6000
Magnesium stearate
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 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

Product imported from the UK:

30 tablets in a white tablet container equipped with a flow reducer and a blue opaque stopper containing a white dessicant gel.

Product imported from Hungary:

30 tablets in a white tablet container equipped with a flow reducer and a white opaque stopper containing a white dessicant gel.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/067/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 6th June 2008

10 DATE OF REVISION OF THE TEXT

November 2014