

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Coversyl Arginine Plus 10mg/2.5mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 6.79 mg perindopril equivalent to 10 mg perindopril arginine and 2.5 mg indapamide.

Excipient: lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Hungary:
White, round film-coated tablet.

4 CLINICAL PARTICULARS

As per PA 0568/022/002

5 PHARMACOLOGICAL PROPERTIES

As per PA 0568/022/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Lactose monohydrate
Magnesium stearate (E470B)
Maltodextrin
Silica colloidal anhydrous (E551)
Sodium starch glycolate (type A)
Microcrystalline cellulose
Film-coating:
Glycerol (E422)
Hypromellose (E464)
Macrogol 6000
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

30 tablets in a container equipped with a flow reducer and a stopper containing a white desiccant gel.

Pack sizes: 1 x 30 tablets

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10 Ashbourne Business Park
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 0465/067/007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th June 2012

10 DATE OF REVISION OF THE TEXT

February 2016