

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 PA0568/022/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0568/022/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

lactose monohydrate

maltodextrin

magnesium stearate (E470B)

anhydrous colloidal silica

Sodium starch glycolate type A

Film-coating:

glycerol (E422)

hypromellose (E464)

macrogol 6000

titanium dioxide (E171)

magnesium stearate (E470B)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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 polypropylene tablet container equipped with a low density polyethylene flow reducer and a low density polyethylene stopper containing a white desiccant gel.

Pack size 1 x 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/063/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT