

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Coverdine 5 mg/1.25 mg/5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 3.395 mg perindopril equivalent to 5 mg perindopril arginine, 1.25 mg indapamide and 6.935 mg amlodipine besilate equivalent to 5 mg of amlodipine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Lithuania:

White, oblong, film-coated tablet, 9.75 mm long and 5.16 mm wide engraved with  on one face and  on the other face.

4 CLINICAL PARTICULARS

As per PA0568/024/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0568/024/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Calcium carbonate starch compound: Calcium carbonate 90%, Pregelatinised maize starch 10%
Cellulose microcrystalline (E460),
Croscarmellose sodium (E468),
Magnesium stearate (E572),
Colloidal anhydrous silica,
Pregelatinised starch

Film-coating:

Glycerol (E422),
Hypromellose 6mPa.s (E464),
Macrogol 6000,
Magnesium stearate (E572),
Titanium dioxide (E 171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

For the container of 30 film-coated tablet, the in-use stability after first opening is 30 days.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

30 film-coated tablets in polypropylene tablet container equipped with a low density polyethylene flow reducer and a low density polyethylene stopper containing a desiccant.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/513/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th January 2025

10 DATE OF REVISION OF THE TEXT