Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Coverdine 10mg/2.5mg/10mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 6.790 mg perindopril equivalent to 10 mg perindopril arginine, 2.5 mg indapamide and 13.870 mg amlodipine besilate equivalent to 10 mg of amlodipine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Latvia.

A white, oblong, film-coated tablet, 12.2 mm long and 6.46 mm, engraved with  on one face and  on the other face.

4 CLINICAL PARTICULARS

As per PA0568/024/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0568/024/005

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

Unopened: The shelf life expiry date for this product shall be the date shown on the container label and outer package of the product on the market in the country of origin.

Opened: 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.
Box of 60 (2 tablet containers of 30), 90 (3 tablet containers of 30).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th December 2022

10 DATE OF REVISION OF THE TEXT

October 2023