

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Coverdine 5 mg/1.25 mg/10 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 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 Lithuania:*

white, oblong, film-coated tablet, 10.7 mm long and 5.66 mm wide engraved with



on one face and



on the other face.

## 4 CLINICAL PARTICULARS

As per PA0568/024/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0568/024/003

## 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 (E171)

### 6.2 Incompatibilities

Not applicable

### **6.3 Shelf life**

Unopened: The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed 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.

### **6.6 Special precautions for disposal**

No special requirements

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.,  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/237/003

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14<sup>th</sup> November 2025

## **10 DATE OF REVISION OF THE TEXT**