

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lipocomb 10 mg/10 mg hard capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 10 mg rosuvastatin (as zinc) and 10 mg of ezetimibe.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsules, hard.

*Product imported from Poland*

Unmarked self-closing Coni Snap type, hard gelatin capsule with yellow coloured cap and yellow coloured body.

## 4 CLINICAL PARTICULARS

As per PA1470/004/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1470/004/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Core:

Silicified microcrystalline cellulose (microcrystalline cellulose (E460) and Colloidal anhydrous silica (E551))

Colloidal anhydrous silica (E551)

Magnesium stearate (E572)

Povidone (E 1201)

Croscarmellose sodium (E468)

Microcrystalline cellulose (E460)

Mannitol (E421)

Sodium laurilsulfate (E514)

Low-substituted hydroxypropyl cellulose (E463)

#### Capsule shell:

Cap and body:

Yellow iron oxide (E172)

Titanium dioxide (E171)

Gelatine

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer package of the product as marketed in the country of origin.

#### **6.4 Special precautions for storage**

Store below 30 °C. Store in the original package in order to protect from light and moisture.

#### **6.5 Nature and contents of container**

Pack of 30 hard capsules in cold-formed foil blister (OPA/Al/PVC//Al)

#### **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**

PPA0465/460/001

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

Date of first authorisation: 5<sup>th</sup> March 2021

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

January 2024