

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 and Czech Republic

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: 5th March 2021

10 DATE OF REVISION OF THE TEXT

September 2025