Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipantil Micro 200 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 200 mg fenofibrate.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule.
Product imported from Poland:
Ochre hard gelatin capsule.

4 CLINICAL PARTICULARS

As per PA2010/015/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/015/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients:
Lactose monohydrate
Magnesium stearate
Pregelatinised maize starch
Sodium laurilsulfate
Crospovidone.

Capsule shell:
Gelatin
Titanium dioxide (E171)
Red iron oxide (E172)
Yellow iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store in the original package in order to protect from moisture. Do not store above 25°C.

6.5 Nature and contents of container

Blister strips in a pack of 30 capsules.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/471/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th February 2022

10 DATE OF REVISION OF THE TEXT