Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipantil Supra 145 mg film-coated tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 145.0 mg fenofibrate (nanoparticles).

Excipients with known effect: each tablet contains:
- Lactose monohydrate
- Sucrose
- Soybean lecithin.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Product imported from France and Spain;
White, oblong, film-coated tablets engraved "145" on one side and "Fournier logo" on the other side.

4 CLINICAL PARTICULARS

As per PA2010/015/003

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/015/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Sucrose
Lactose monohydrate
Silicified microcrystalline cellulose
Crospovidone
Hypromellose
Sodium lauril sulfate
Docusate sodium
Magnesium stearate

Coating Opadry also contains:
polyvinyl alcohol
titanium dioxide (E 171)
talc
soybean lecithin
xanthan gum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer carton 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

Blister strips in a pack of 30 tablets.

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

PPA0465/409/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: May 2015
Last updated: November 2016

10 DATE OF REVISION OF THE TEXT

February 2022