Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipantil Supra 145mg film-coated tablets

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
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
Microcrystalline cellulose and colloidal anhydrous silica
Crospovidone
Hypromellose
Sodium lauril sulfate
Docusate sodium
Magnesium stearate

Coating:
Polyvinyl alcohol
Titanium dioxide (E171)
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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C
Store in the original packaging.

6.5 Nature and contents of container

Thermoformed blister strips (clear PVC/PE/PVDC sealed with aluminium complex).

Boxes 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

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/124/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 2014

10 DATE OF REVISION OF THE TEXT

April 2018