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: soybean lecithin, lactose monohydrate and sucrose
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.
Product imported from 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 laurilsulfate
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

Store below 30°C.

6.5 Nature and contents of container

Pack size: 30 tablets in blister (PVC/aluminium) repackaged in an overlabelled outer cardboard box.

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

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex
UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/036/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th April 2015

10 DATE OF REVISION OF THE TEXT

July 2017