Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lipantil Supra 145 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 145.0mg of fenofibrate (nanoparticles).
Excipients with known effect: lactose monohydrate, sucrose, soya 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 PA2007/012/003

5 PHARMACOLOGICAL PROPERTIES

As per PA2007/012/003

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
Soya lecithin
Xanthan gum.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Do not store above 30°C.

6.5 Nature and contents of container

Blister packs of 30 tablets (3 blister strips of 10 tablets).
Blister packs of 90 tablets (9 blister strips of 10 tablets).

6.6 Special precautions for disposal and other handling

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/180/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 2012

10 DATE OF REVISION OF THE TEXT

February 2017