

# 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 PA2007/012/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2007/012/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Core:

Sucrose  
Lactose monohydrate  
Silicified microcrystalline cellulose  
Crospovidone  
Hypromellose  
Sodium lauryl 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

Last updated: January 2022

## **10 DATE OF REVISION OF THE TEXT**

September 2024