

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lipantil Micro 200mg capsules, hard

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 200mg fenofibrate.

Excipients with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, hard.

*Product imported from Spain:*

Ochre hard gelatin capsule.

## 4 CLINICAL PARTICULARS

As per PA2010/015/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2010/015/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Excipients:

Lactose monohydrate

Magnesium stearate

Pregelatinised maize starch

Sodium laurilsulfate

Crospovidone.

#### Capsule shell:

Gelatin

Titanium dioxide (E 171)

Red iron oxide (E 172)

Yellow iron oxide (E172)

## **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 in the original package in order to protect from moisture.

Do not store above 30°C.

#### **6.5 Nature and contents of container**

Pack size: 30 capsules in blister (PVC/aluminium) contained in a repackaged 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**

PPA1633/036/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 17<sup>th</sup> April 2015

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

November 2018