Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lopid 600 mg film-coated tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 600 mg of gemfibrozil.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Spain and Germany:
Lopid 600 mg: white, biconvex, oval, film-coated tablets

4 CLINICAL PARTICULARS

As per PA0822/014/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/014/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product as sourced from Spain:
Core tablet excipients:
Microcrystalline cellulose
Pregelatinised starch
Colloidal anhydrous silica (E551)
Polysorbate 80 (E433)
Sodium starch glycollate
Magnesium stearate (E470b)

Tablet coating:
Hypromellose (E464)
Titanium dioxide (E171)
Talc (E553b)
Simethicone
Macrogol 6000

Product as sourced from Germany:
Core tablet excipients:
Microcrystalline cellulose
Pregelatinized starch from corn
Colloidal anhydrous silica (E551)
Polysorbate 80 (E433)
Sodium starch glycollate
Magnesium stearate (E470b).

Tablet coating:
Hypromellose (E464)

Titanium dioxide (E171)
Talc (E553b)
Dimeticone
Macrogol 6000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/aluminium blisters with 60 tablets in a cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/320/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th July 2013

10 DATE OF REVISION OF THE TEXT

June 2023