

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lopid 600mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 600 mg gemfibrozil.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Product imported from Spain:
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

Core tablet excipients:
Microcrystalline cellulose
Pregelatinized starch
Colloidal silica (anhydrous) (E551)
Polysorbate 80 (E433)
Sodium starch glycollate
Magnesium stearate (E460i)

Tablet coating:
Hypromellose (E464)
Titanium dioxide (E171)
Talc (E553b)
Simethicone (E900)
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

Store below 25°C.

6.5 Nature and contents of container

PVC/Auminium blisters with 60 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/165/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th January 2012

10 DATE OF REVISION OF THE TEXT

March 2015