Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lustral 50mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg sertraline (as hydrochloride).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK
White, capsule shaped, film coated, scored tablets coded 'ZLT 50' on one side and 'PFIZER' on the other.

Product imported from Spain
White, capsule shaped, film-coated, scored tablets coded 'ZLT-50' on one side and 'PFIZER' on the other.
The tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0822/001/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/001/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from the UK
Tablet Core:
Calcium hydrogen phosphate
Microcrystalline cellulose
Hydroxypropylcellulose
Sodium starch glycolate (Type A)
Magnesium stearate
Macrogol

Film Coating:
Titanium dioxide (E171)
Hypromellose
Macrogol
Polysorbate 80

Product imported from Spain
Calcium hydrogen phosphate dihydrate (E341)
Microcrystalline cellulose (E460)
Hydroxypropylcellulose (E463)
Sodium starch glycolate
Magnesium stearate (E572)
Hypromellose (E464)
Macrogol
Polysorbate-80 (E433)

Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is 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

Do not store above 30 °C.

6.5 Nature and contents of container

Overlabelled carton or carton containing blister strips
Pack size: 28 tablets *(product imported from the UK)*, 30 tablets *(product imported from Spain)*
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 MARKETING AUTHORISATION NUMBER

PPA1151/002/002

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/002/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 January 2005

Date of last renewal: 07 January 2010

10 DATE OF REVISION OF THE TEXT

March 2019