Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lustral 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains sertraline hydrochloride equivalent to 50 mg sertraline.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK:
White, capsular shaped, film-coated scored tablets marked 'LTL 50' on one side and 'PFIZER' on the other side.

Product imported from The Netherlands, Hungary, Italy, Spain, Romania, Portugal and Poland:
White, capsular shaped, film-coated scored tablets marked 'ZLT 50' on one side and 'PFIZER' on the other side.

The tablet can be divided into equal doses

4 CLINICAL PARTICULARS

As per PA23055/001/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/001/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate dihydrate (E341)
Microcrystalline cellulose (E460)
Hyprolose (E463)
Sodium starch glycolate (Type A)
Magnesium stearate (E572)
Hypromellose (E464)
Macrogol (E1521)
Polysorbate-80 (E433)
Titanium dioxide (E171).

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

Do not store above 25°C.

6.5 Nature and contents of container

Blister packs of 28 or 30 tablets contained in an outer cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/062/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: January 2020

Date of last renewal: June 2021

10 DATE OF REVISION OF THE TEXT

April 2022