Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lustral 100 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains sertraline hydrochloride equivalent to 100 mg sertraline.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product sourced from Spain, Greece and Romania:
White, capsular shaped, film-coated tablets marked 'ZLT 100' on one side and 'PFIZER' on the other.

Product sourced from Poland, Portugal & Italy:
White, capsular shaped, film-coated tablets coded 'ZLT 100' on one side and 'PFIZER' on the other side.

4 CLINICAL PARTICULARS

As per PA23055/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate
Microcrystalline cellulose
Hyprolose
Sodium starch glycolate
Magnesium stearate
Hypromellose
Macrogol
Polysorbate 80
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

PPA0465/062/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 September 2001

Date of last renewal: 07 September 2006

10 DATE OF REVISION OF THE TEXT

July 2023