

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 50mg 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 and Portugal:

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 PA0822/001/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/001/004

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

PPA0465/062/001

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

May 2020