Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lustral 50 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sertraline hydrochloride equivalent to 50mg sertraline.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Italy:
White, capsular-shaped, film-coated scored tablets coded “ZLT-50” on one side and “PFIZER” on the other.

4 CLINICAL PARTICULARS

As per PA0822/001/004.

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/001/004.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet cores:
calcium hydrogen phosphate dihydrate
microcrystalline cellulose
hyprolose
sodium starch glycolate
magnesium stearate
Film Coating:
Hypromellose E3
Hypromellose E5
Macrogol 400
Macrogol 6000
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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs of 30 tablets. Blister strips, each containing 15 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

PPA1328/085/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 20th March 2009

10 DATE OF REVISION OF THE TEXT

April 2015