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 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 the UK and Italy:
White, capsular-shaped, film-coated scored tablets coded “ZLT-50” or "LTL-50" or "SER-50" on one side and “PFIZER” on the other.
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

Tablet Core
Calcium hydrogen phosphate dihydrate (E341)
Microcrystalline cellulose (E460)
Hydroxypropylcellulose (E463)
Sodium starch glycolate
Magnesium stearate (E572)

Film Coating
Opadry White containing
Hypromellose (E464)
Macrogol
Polysorbate-80 (E433)
Titanium dioxide (E171)

Opadry Clear containing:
Hypromellose (E464)
Macrogol

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

Blister strips in an over-labelled cardboard carton.
Pack size: 28 or 30 tablets.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th November 2009

10 DATE OF REVISION OF THE TEXT

October 2014