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 Poland:
White, capsular shaped (10.3 x 4.2 mm), film-coated scored tablets marked 'ZLT 50' on one side and 'PFIZER' on the other. 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)
hydroxypropyl cellulose (E463)
sodium starch glycollate (Type A)
magnesium stearate (E572)
titanium dioxide (E171)
hypromellose 2910, 3 mPas (E464)
hypromellose 2910, 6 mPas (E464)
macrogol 400 (E1521)
polysorbate 80 (E433)
macrogol 8000 (E1521)

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 30^{o}C.

6.5 Nature and contents of container

Tablets are packed in Aluminium/PVC blisters of 28 tablets.

6.6 Special precautions for disposal

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

PPA1463/202/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th July 2023

10 DATE OF REVISION OF THE TEXT