

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lustral 100 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg sertraline (as hydrochloride)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK

White, capsule shaped film-coated tablets coded 'ZLT 100' on one side and 'PFIZER' on the other.

4 CLINICAL PARTICULARS

As per PA0822/001/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/001/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Calcium hydrogen phosphate dihydrate

Microcrystalline cellulose

Hypromellose

Sodium starch glycolate (Type A)

Magnesium stearate

Macrogol

Film Coating:

Titanium dioxide (E171)

Hypromellose

Macrogol

Polysorbate 80

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

Overlabelled carton containing blister strips
Pack size: 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

PPA1463/131/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 January 2005

Date of last renewal: 07 January 2010

10 DATE OF REVISION OF THE TEXT

April 2020