

# 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 50 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, 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

*Product imported from the UK*

Tablet Core:

Calcium hydrogen phosphate  
Microcrystalline cellulose  
Hydroxypropylcellulose  
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 or carton containing blister strips  
Pack size: 28 tablets (*product imported from the UK*),  
Not all pack sizes may be marketed.

**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**

PPA1463/131/002

**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**

October 2020