

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lustral 100mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sertraline hydrochloride equivalent to 100mg sertraline.  
For 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-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 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 15 and 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**

PPA1328/085/002

## **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