

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lexapro 15 mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 15 mg escitalopram (as oxalate)

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated Tablets

*Product imported from France:*

Oval, white, scored, film-coated tablet marked with "EM" on one side.

The tablet can be divided into equal halves.

## 4 CLINICAL PARTICULARS

As per PA0805/002/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0805/002/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core:

Microcrystalline cellulose

Colloidal anhydrous silica

Talc

Croscarmellose sodium

Magnesium stearate

Coating:

Hypromellose

Macrogol 400

Titanium dioxide (E 171)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

### 6.4 Special precautions for storage

No special precautions for storage.

#### **6.5 Nature and contents of container**

Over-labelled carton containing two transparent blister strips (14 tablets per strip)  
Pack size of 28 tablets

#### **6.6 Special precautions for disposal and other handling**

No special requirements.

#### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Merit Pharmaceuticals Limited  
Unit C4 Metropoint Business Park  
Kettles Lane  
Swords  
Co Dublin  
K67 RH92  
Ireland

#### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23080/005/001

#### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 20<sup>th</sup> May 2011

#### **10 DATE OF REVISION OF THE TEXT**

May 2021