

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cipramil 20 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg citalopram (as citalopram hydrobromide).

Excipient(s) with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Spain, United Kingdom, France, Hungary, The Netherlands and Italy:*

White, oval-shaped tablets plain on one side and with a breakline on the other side. 'C' is debossed to the left of the breakline and 'N' is debossed to the right of the breakline.

## 4 CLINICAL PARTICULARS

As per PA0776/001/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0776/001/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Maize starch  
Lactose monohydrate  
Cellulose, microcrystalline  
Copovidone  
Glycerol 85%  
Croscarmellose sodium  
Magnesium stearate  
Hypromellose  
Macrogol 400  
Titanium dioxide (E 171)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister pack and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 25 °C.

Store in the original package in order to protect from light.

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

Blister packs of 28 tablets in a cardboard outer carton or an overlabelled outer carton.

#### **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**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

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

PPA0465/068/002

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

Date of first authorisation: 24 August 2001

Date of last renewal: 24 August 2006

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

November 2019