

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Seroxat 20mg Film-coated Tablets.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 mg paroxetine (as paroxetine hydrochloride hemihydrate).

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

*Product imported from France:*

Film-coated Tablet

White, oval, film-coated tablets, engraved '20' on one side and having a breakline on the reverse.

*Product imported from Greece and The Netherlands:*

Film-coated Tablet

White, oval, film-coated tablets, engraved '20' on one side and having a breakline on the reverse.

*Product imported from the United Kingdom:*

Film-coated Tablet

White, oval, film-coated tablets, engraved '20' on one side and having a breakline on the reverse.

### 4 CLINICAL PARTICULARS

As per PA1077/097/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/097/002

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

*Product as sourced from France, Greece, the Netherlands and the UK:*

##### Tablet core

Dibasic calcium phosphate dihydrate

Magnesium stearate

Sodium starch glycolate (Type A)

##### Tablet coating

Hypromellose

Macrogol 400

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

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

Blister packs of 14 and 30 tablets in an overlabelled outer carton.

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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/055/001

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

Date of first authorisation: 22 December 1999

Date of last renewal: 22 December 2009

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

September 2015