Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroxat 20 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Romania
White, film-coated tablet, oval shaped biconvex tablets debossed with "20" on one side and a break bar on the other.

The 20 mg tablet can be divided into equal doses if required.

4 CLINICAL PARTICULARS

As per PA1077/097/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/097/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Dibasic calcium phosphate dihydrate (E341)
Sodium starch glycolate (Type A)
Magnesium stearate (E470b).

Tablet coating:
Hypromellose (E464)
Macrogol 400
Polysorbate 80 (E433)
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 blister 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 ºC.
Store in the original package in order to protect from light.

6.5 Nature and contents of container

Child-resistant blister packs comprising opaque polyvinyl chloride (PVC) backed with aluminium foil laminated with paper. Pack sizes: 30 tablets.

6.6 Special precautions for disposal

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

PPA0465/483/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th November 2021

10 DATE OF REVISION OF THE TEXT

April 2023