

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 a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK:

White, oval shaped, biconvex film-coated tablet debossed with "SEROXAT 20" on one side and a break line on the other.

The 20mg film-coated tablet has a break-line and can be divided into equal halves if required.

4 CLINICAL PARTICULARS

As per PA1077/097/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/097/002

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

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 container and outer packaging 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 in order to protect from light.

6.5 Nature and contents of container

Over-labelled cartons containing 3 blister strips (10 tablets per strip). Pack size of 30 tablets.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 12th December 2008

10 DATE OF REVISION OF THE TEXT

October 2019