

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 the UK:

White, film-coated oval tablets, debossed with "SEROXAT 20" or "20" on one side and a break bar 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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Dibasic calcium phosphate dihydrate (E341)

Magnesium stearate (E470b)

Sodium starch glycolate (Type A)

Tablet coating:

Hypromellose (E464)

Titanium dioxide (E171)

Macrogol 400

Polysorbate 80 (E433)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the container 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 in order to protect from light.

6.5 Nature and contents of container

Blister packs comprising opaque PVC/PVdC or opaque polyvinyl chloride (PVC) backed with aluminium foil. Pack size: 30

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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th August 2011

10 DATE OF REVISION OF THE TEXT

October 2018