

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 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 tablets debossed with "20" on one side and a break bar on the other.
The 20 mg film-coated tablet has a break-line, and can be divided into equal halves if required.

4 CLINICAL PARTICULARS

As per PA 1077/097/002

5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/097/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic calcium phosphate dihydrate
Magnesium stearate
Sodium starch glycolate
Hypromellose
Titanium dioxide (E171)
Macrogol
Polysorbate

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 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 foil packs in a cardboard carton.
Pack size: 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 9th November 2007

10 DATE OF REVISION OF THE TEXT

October 2014