

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroxat 30 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 30mg 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:

Blue, oval shaped biconvex tablets debossed with “SEROXAT 30” or ‘30’ on one side and a break bar on the other.

4 CLINICAL PARTICULARS

As per PA 1077/097/003

5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/097/003

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)

Indigo carmine (E132)

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 and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/034/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st January 2011

10 DATE OF REVISION OF THE TEXT

October 2014