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 30 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

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

The break bar is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1077/097/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/097/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Tablet coating:
Hypromellose (E464)
Titanium dioxide (E171)
Macgrogol 400
Polysorbate 80 (E433)
Indigo carmine

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 30ºC.
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 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

LTT Pharma Limited
Unit 18 Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/030/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th August 2011

10 DATE OF REVISION OF THE TEXT

July 2016