Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Citalopram 20 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains citalopram hydrobromide equivalent to 20mg citalopram.

Excipients with known effect: contains lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK:
White, oval, normal convex film-coated tablets debossed with “CM" scoreline "20” on one side and “G” on the other. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0577/047/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0577/047/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Lactose monohydrate
Maize starch
Microcrystalline cellulose
Povidone
Crospovidone
Magnesium stearate

Tablet Coating
Titanium dioxide (E 171)
Lactose monohydrate
Macrogol 4000
Hypromellose (E464)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister strips in an outer carton. Pack size: 28 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

WPR Healthcare Limited
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th August 2011

10 DATE OF REVISION OF THE TEXT

April 2016