Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Escitalpro 20mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Escitalpro 20 mg film-coated tablets: each tablet contains 20 mg escitalopram (as oxalate)

Excipient with known effect: 20 mg film-coated tablets contain lactose (as lactose monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK:
Escitalpro 20 mg film-coated tablets: oblong, white, scored film-coated tablet marked with "EC|20 " on one side and “G” on the other. The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA0577/108/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0577/108/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Microcrystalline cellulose
Colloidal anhydrous silica
Talc
Croscarmellose sodium
Magnesium stearate

Coating:
Lactose monohydrate
Macrogol 4000
Titanium dioxide (E171)
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Store below 25°C. Store in the original package.

6.5 Nature and contents of container

Blister packs of 28 tablets contained in a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/055/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st of May 2015

10 DATE OF REVISION OF THE TEXT