Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lexapro 5mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5mg escitalopram (as oxalate).

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK:
Round, white biconvex tablet marked with 'EK' on one side.

4 CLINICAL PARTICULARS

As per PA0805/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0805/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Colloidal anhydrous silica
Talc
Crosarmellose sodium
Magnesium Stearate
Hypromellose
Macrogol 400
Titanium dioxide (E171)

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs of 28 tablets contained in an outer cardboard carton.

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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/129/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 February 2006

Date of last renewal: 10 February 2011

10 DATE OF REVISION OF THE TEXT

February 2016