Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lexapro 10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg escitalopram (as oxalate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from Spain, Italy, France and the Czech Republic:

Oval, white, scored, film-coated tablet marked with 'E' and 'L' on each side of the score on one side of the tablet.

The tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0805/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0805/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Colloidal anhydrous silica
Talc
Croscarmellose 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 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

This medicinal product does not require any special storage precautions.

6.5 Nature and contents of container

Blister packs of 28 tablets contained in an over-labelled 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 Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/129/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th March 2005

Date of last renewal: 18th March 2010

10 DATE OF REVISION OF THE TEXT

April 2024