

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lexapro 15 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 15 mg escitalopram (as oxalate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Spain, France and The Netherlands:

Oval, white, scored, film-coated tablet marked with "E" and "M" 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 PA0805/002/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0805/002/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Microcrystalline cellulose

Colloidal anhydrous silica

Talc

Croscarmellose sodium

Magnesium stearate

Coating:

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 conditions.

6.5 Nature and contents of container

Aluminium 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/129/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th July 2011

10 DATE OF REVISION OF THE TEXT

May 2020