Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lexapro 5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg escitalopram (as oxalate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Austria:

Round, white, film-coated tablet of 6mm 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

Tablet core:
Microcrystalline cellulose, silicified
Talc
Croscarmellose sodium
Magnesium stearate

Coating:
Hypromellose
Macrogol 400
Titanium dioxide (E 171)

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

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

PPA0465/129/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th April 2025

10 DATE OF REVISION OF THE TEXT