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 France:
Oval, white film-coated tablets of 9.8 x 6.3 mm. The tablets are scored and marked with "E" and "M" on each side of the score on one side of the tablet.

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 (E 171)

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/241/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th April 2025

10 DATE OF REVISION OF THE TEXT