

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Campral EC 333mg Gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains acamprosate calcium 333.0 mg

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet

Product imported from Belgium:

White coated gastro-resistant tablet with '333' engraved on one side.

4 CLINICAL PARTICULARS

As per PA2286/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2286/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crospovidone
Microcrystalline cellulose
Magnesium silicate
Sodium starch glycolate Type A
Anhydrous colloidal silica
Magnesium stearate
Eudragit L30D
Talc
Propylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Each carton contains 84 or 168 tablets. Each blister contains 12 or 20 tablets.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/504/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 2024

10 DATE OF REVISION OF THE TEXT

June 2025