

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Campral EC 333 mg 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 tablets. Each blister contains 12 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: 26<sup>th</sup> January 2024

**10 DATE OF REVISION OF THE TEXT**