

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 a 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 container 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

PVC/PVDC aluminium sheets of blister containing 12 tablets. Sheets of blister are presented in cartons of 84 tablets.

6.6 Special precautions for disposal

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

PPA1463/177/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd July 2021

10 DATE OF REVISION OF THE TEXT