

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 a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-Resistant Tablet

Product imported from The Netherlands

White coated gastro-resistant round tablet with 333 on one side and blank on the other 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
colloidal silicon dioxide
magnesium stearate
polyacrylate (Eudragit L30D)
Talc
propylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

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

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/178/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th August 2016

10 DATE OF REVISION OF THE TEXT

November 2018