

## Package Leaflet: Information for the user

### Campral® EC 333mg gastro-resistant tablets (acamprosate calcium)

The name of your medicine is Campral EC 333mg gastro-resistant tablets, which will be referred to as Campral tablets throughout this leaflet. 'EC' stands for 'Enteric coated' which is a type of gastro-resistant tablet.

### Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Campral tablets are and what they are used for
2. What you need to know before you take Campral tablets
3. How to take Campral tablets
4. Possible side effects
5. How to store Campral tablets
6. Contents of the pack and other information

### 1. What Campral tablets are and what they are used for

Campral tablets are a medicine which acts on the central nervous system (the brain and the spinal cord).

Campral tablets help people who are dependent on alcohol to abstain from drinking alcoholic drinks. Campral tablets in combination with counselling will help you not to drink alcohol. It does this by acting on the chemical changes that have taken place in the brain during the years that you have been drinking alcohol. It does not prevent the harmful effects of continuous alcohol abuse.

### 2. What you need to know before you take Campral tablets

#### Do not take Campral tablets:

- if you have had an allergic reaction, skin rash, swelling of the face, wheezing or difficulty breathing after taking acamprosate (INN) calcium or any of the other ingredients of Campral tablets (see list of ingredients in section 6) in the past
- if you are pregnant or breast-feeding
- if you suffer from severe kidney disease
- if you suffer from severe liver disease

#### Warnings and precautions

Tell your doctor or pharmacist before taking Campral tablets.

#### You should not be drinking when you start Campral tablets treatment. Campral tablets will be less effective if you keep drinking.

If you drink too much alcohol, your body system and in particular your nervous system adapt to the effects of alcohol. When you then suddenly stop drinking you may experience some unpleasant symptoms known as alcohol withdrawal syndrome, which can last up to two weeks.

You should take Campral tablets as soon as possible after the withdrawal period.

Because patients who suffer from alcohol dependence often also suffer from depression it is recommended that you be monitored for symptoms of depression.

This medicine is not recommended for children or elderly.

#### Other medicines and Campral tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Campral tablets have often been given to patients together with other medicines that are used to treat alcohol withdrawal or maintain abstinence. So far, Campral tablets do not seem to interfere with the effects of other medicines, however if you are prescribed diuretics (water tablets) consult your doctor.

#### Campral tablets with alcohol

**Drinking alcohol while taking Campral tablets does not make you feel sick, however do not drink alcohol at all during your treatment with Campral tablets.** Even if you drink a small amount of alcohol you run the risk of making your treatment fail and you may end up drinking heavily again.

### Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, or planning to become pregnant, you should not take Campral tablets without consulting your doctor first.

If you are breast-feeding, you should not take Campral tablets.

### Driving and using machines

Campral tablets do not make you sleepy and therefore is not expected to affect your ability to drive or use machines.

### Information about sodium content

This medicine contains less than 1mmol sodium (23mg) per dosage unit, that is to say it is essentially 'sodium free'.

### 3. How to take Campral tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### The recommended dose

If you weigh 60kg or more:  
The usual dose is 6 tablets a day: 2 tablets in the morning, 2 tablets at noon and 2 tablets in the evening with meals.

If you weigh less than 60kg:  
The usual dose is 4 tablets a day: 2 in the morning, 1 at noon and 1 in the evening with meals.

#### Duration of treatment:

It is recommended that you keep taking Campral tablets for one year.

#### If you take more Campral tablets than you should

If you take too many tablets, call your doctor or hospital casualty department immediately. You may experience diarrhoea and have raised blood calcium levels.

#### If you forget to take Campral tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

#### If you stop taking Campral tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you experience any of the following side effects with Campral tablets, STOP taking the tablets and contact your doctor immediately: A severe allergic reaction, such as angio-oedema (causing large raised marks on the skin and localised swelling, including the face and throat) or anaphylaxis (causing difficulty in breathing with rash, swelling, wheezing and feeling faint).**

The following side-effects have been reported:

Very common: may affect more than 1 in 10 people

- diarrhoea

Common: may affect up to 1 in 10 people

- stomach ache
- gas
- feeling sick
- vomiting
- itchy or spotty skin rash
- decreased sexual desire
- impotence
- frigidity

Uncommon: may affect up to 1 in 100 people

- increased sexual desire

Not Known: frequency cannot be estimated from the available data

- allergic reactions including hives, angio-oedema and anaphylaxis (see the beginning of this section)
- blistering rash characterised by patches of skin filled with fluid

#### Reporting side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store Campral tablets

- **Keep out of the sight and reach of children.**
- Do not store above 25°C.
- Do not use the medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.
- If the tablets become discoloured or show signs of deterioration, you should seek the advice of your pharmacist.
- If your doctor decides to stop your treatment, take any tablets you have left back to the pharmacy.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Campral tablets contain

The active ingredient is acamprosate calcium. Each gastro-resistant tablet contains 333mg acamprosate calcium.

Also contains crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycollate, silica colloidal anhydrous, magnesium stearate, Eudragit L30D, talc and propylene glycol.

##### What Campral tablets look like and contents of the pack

Campral tablets are round, white tablet marked with '333' on one side and plain on the reverse

Campral tablets are supplied in packs of 168 tablets.

##### Manufacturer

Manufactured by: Merck Santé s.a.s., Centre de production, 2, rue du Pressoir Vert, 45400 SEMOY, France.  
Or  
Merck SL, Poligono Merck Mollet Del Valles, 08100 Barcelona, Spain.

Procured from within the EU and repackaged by:  
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall,  
Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharma Limited,  
Crompton Road, Doncaster, DN2 4PW, UK.

PL: 56830/0029

POM

Leaflet revision & issue date (Ref): 11.11.22

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Blind or partially sighted?  
Is this leaflet hard to see or read?

Call +44 (0) 1302 365000  
(Regulatory)

Please be ready to give the following information:

Product name:

Campral EC 333mg

gastro-resistant tablets

Reference No: 56830/0029

## Package Leaflet: Information for the user

### **Acamprosate Calcium 333mg gastro-resistant tablets** (Acamprosate)

The name of your medicine is Acamprosate Calcium 333mg gastro-resistant tablets, which will be referred to as Acamprosate tablets throughout this leaflet.

#### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

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#### **What is in this leaflet**

1. What Acamprosate tablets are and what they are used for
2. What you need to know before you take Acamprosate tablets
3. How to take Acamprosate tablets
4. Possible side effects
5. How to store Acamprosate tablets
6. Contents of the pack and other information

#### **1. What Acamprosate tablets are and what they are used for**

Acamprosate tablets are a medicine which acts on the central nervous system (the brain and the spinal cord).

Acamprosate tablets help people who are dependent on alcohol to abstain from drinking alcoholic drinks. Acamprosate tablets in combination with counselling will help you not to drink alcohol. It does this by acting on the chemical changes that have taken place in the brain during the years that you have been drinking alcohol. It does not prevent the harmful effects of continuous alcohol abuse.

#### **2. What you need to know before you take Acamprosate tablets**

##### **Do not take Acamprosate tablets:**

- if you have had an allergic reaction, skin rash, swelling of the face, wheezing or difficulty breathing after taking acamprosate (INN) calcium or any of the other ingredients of Acamprosate tablets (see list of ingredients in section 6) in the past
- if you are pregnant or breast-feeding
- if you suffer from severe kidney disease
- if you suffer from severe liver disease

##### **Warnings and precautions**

Tell your doctor or pharmacist before taking Acamprosate tablets.

##### **You should not be drinking when you start Acamprosate tablets treatment. Acamprosate tablets will be less effective if you keep drinking.**

If you drink too much alcohol, your body system and in particular your nervous system adapt to the effects of alcohol. When you then suddenly stop drinking you may experience some unpleasant symptoms known as alcohol withdrawal syndrome, which can last up to two weeks.

You should take Acamprosate tablets as soon as possible after the withdrawal period.

Because patients who suffer from alcohol dependence often also suffer from depression it is recommended that you be monitored for symptoms of depression.

This medicine is not recommended for children or elderly.

##### **Other medicines and Acamprosate tablets**

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##### **Acamprosate tablets with alcohol**

**Drinking alcohol while taking Acamprosate tablets does not make you feel sick, however do not drink alcohol at all during your treatment with Acamprosate tablets.**

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##### **Pregnancy and breast-feeding**

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##### **Driving and using machines**

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##### **Information about sodium content**

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##### **Duration of treatment:**

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If you take too many tablets, call your doctor or hospital casualty department immediately. You may experience diarrhoea and have raised blood calcium levels.

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Or  
Merck SL, Poligono Merck Mollet Del Valles, 08100 Barcelona, Spain.

Procured from within the EU and repackaged by:  
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall,  
Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharma Limited,  
Crompton Road, Doncaster, DN2 4PW, UK.

PL: 56830/0029

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Acamprosate Calcium 333mg  
gastro-resistant tablets

Reference No: 56830/0029