Package leaflet: Information for the user

Campral EC
Acamprosate calcium

The name of your medicine is Campral EC 333 mg 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 is a medicine which acts on the central nervous system (the brain and the spinal cord).
Campral helps people who are dependent on alcohol to abstain from drinking alcoholic drinks. Campral 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 (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 treatment. Campral 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 has often been given to patients together with other medicines that are used to treat alcohol withdrawal or maintain abstinence. So far, Campral does 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 does not make you feel sick, however do not drink alcohol at all during your treatment with Campral. 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 breastfeeding, you should not take Campral tablets.

Driving and using machines
Campral does 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 60 kg 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 60 kg
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 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 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 this medicine out of the sight and reach of children.
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.
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 substance is acamprosate calcium. Each tablet contains 333 mg acamprosate calcium, equivalent to 300 mg of acamprosate.
The other ingredients are Crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycolate, anhydrous colloidal silica, magnesium stearate, anionic copolymer of methacrylic acid and acid ethyl ester, talc and propylene glycol (inactive ingredients).

What Campral tablets look like and contents of the pack
Campral tablets are white and round with '333' engraved on one side and approximately 10 mm in diameter.
They are packed in blister strips and supplied in boxes of 168 tablets.

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