

Campral(R)

contains the active ingredient *acamprosate calcium*

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Campral.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Campral against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Campral is used for

Campral is used in the treatment of alcohol dependence. It helps people who are dependent on alcohol to abstain from drinking alcoholic beverages.

Alcohol dependence is an illness that can and should be treated. Drinking too much alcohol may harm your health and cause physical, psychological and social problems. If this happens to you, your doctor may advise you to stop drinking alcohol altogether.

If you drink too much alcohol, your body and nervous system adapt to its effects. When you suddenly stop drinking, you may experience some unpleasant symptoms (known as

alcohol withdrawal syndrome or the "shakes"), which can last up to 2 weeks.

During alcohol withdrawal, you may feel shaky, have an upset stomach, a fast heart beat and high blood pressure. You may also feel anxious, down, or be in a bad mood.

Sometimes, you may see things that are not there, or suffer from a headache or not be able to sleep.

If these symptoms are severe, you may need observation in hospital.

After going through this difficult period, your doctor will encourage you to live without alcohol through counselling. Campral, in combination with counselling from a general practitioner, psychiatrist, psychologist, or a drug and alcohol counsellor, will help you to stop yourself from starting to drink again.

Campral works by acting on certain chemical changes that have taken place in your brain over the time that you have been drinking alcohol.

Campral is not recommended for use in children or elderly patients.

Campral is available only with a doctor's prescription.

There is no evidence that Campral is addictive.

Before you take Campral

When you must not take it

Do not take Campral if you are allergic to acamprosate calcium or any of the ingredients listed at the end of this leaflet.

Do not take Campral if:

- * you have kidney disease
- * you have severe liver disease.

Do not take Campral if you are pregnant.

The safety of Campral has not been established in pregnant women.

Do not take Campral if you are breastfeeding.

Like many other medicines, Campral can pass into breast milk and may affect your baby .

Do not take Campral if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Campral if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

As Campral does not treat the symptoms of alcohol withdrawal, it is recommended that you start Campral:

- * after you have stopped drinking; and
- * as soon as the withdrawal symptoms have ended.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have any other health problems or medical conditions.

Tell your doctor if you plan to become pregnant or breastfeed.

If you have not told your doctor about any of the above, tell them before you start taking Campral.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to take Campral

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The usual dose for adults weighing 60 kg or more is 2 tablets three times daily with meals.

For adults weighing less than 60 kg, the recommended dose is 2 tablets in the morning, 1 tablet at midday and 1 tablet at night. These doses are also to be taken at meal times.

How to take Campral

Swallow the tablets whole with a glass of water.

Do not break, crush or chew the tablets.

The tablets have a special coating to prevent stomach upset.

If you forget to take Campral

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take Campral for

Campral is usually taken for one year.

Keep taking Campral for as long as your doctor recommends.

If you take too much Campral (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), if you think you or anyone else may have taken too much Campral. Do this even if there are no signs of discomfort or poisoning.

While you are taking Campral

Things you must do

It is important to continue taking Campral even if you have a short relapse.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Campral.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Campral.

If you become pregnant while taking Campral, tell your doctor immediately.

Things you must not do

Do not use Campral to treat any other conditions unless your doctor tells you to.

Do not give Campral to anyone else, even if they have the same condition as you.

Things to be careful of

Drinking alcohol while taking Campral will not make you feel sick. However, you are advised not to drink alcohol at all during your treatment with Campral. Even if you only drink a little alcohol, you run the risk of making your treatment fail.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Campral.

Campral helps most people with alcohol dependence, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- * diarrhoea
- * nausea (feeling sick), vomiting, upset stomach
- * itching, skin rash
- * changes in sex drive.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After using Campral

Storage

Keep Campral where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Campral or any other medicine in the bathroom or near a sink.

Do not leave Campral in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Campral, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Campral is a round, white, enteric-coated tablet, marked "333" on one side.

Each pack contains 180 tablets.

Ingredients

The active ingredient in Campral is acamprosate calcium. Each Campral tablet contains 333 mg of acamprosate calcium.

The tablets also contain:

- * crospovidone
- * microcrystalline cellulose
- * magnesium silicate dihydrate
- * sodium starch glycollate
- * colloidal anhydrous silica
- * magnesium stearate
- * purified talc
- * propylene glycol
- * Eudragit L 30 D-55.

The tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Campral is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

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www.alphapharm.com.au

Medical Information

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Australian registration number:

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