

Package leaflet: information for the patient

Campral, gastro-resistant tablets 333 mg
acamprosate

Read the entire 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.

- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet?
- Please contact your doctor or pharmacist ..

of of this leaflet:

1. What is Campral and what is this medicine used for?
2. When should you not take this medicine or be extra careful with it?
3. How do you take this medicine?
4. Possible side effects.
5. How do you store this medicine?
6. Contents of the package and other information

1. What is Campral and what is this medicine used for?

Campral is a medicine from the group of medicines used for alcohol addiction. Campral reduces the craving for alcohol.

Campral is prescribed for the treatment of chronic alcoholism and serves as support for the psycho-social guidance to prevent renewed alcohol use. The treatment with Campral is started following the detoxification course.

2. When should you not take this medicine or be extra careful?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

In severe kidney problems..

When should you be extra careful with this medicine?

During the physical withdrawal period. It makes no sense to

During the physical withdrawal period. It makes no sense to Campral during this period, as it will have no effect. –

In children or elderly.

In case of kidney problems: in patients with moderate kidney problems, it may be necessary to adjust the dose.

In severe liver problems

In patients with alcohol addiction, symptoms of depression and suicidal thoughts may occur. Contact your doctor immediately if such symptoms occur. Family members and relatives should seek medical advice immediately if these symptoms occur.

Are you taking any other medications?

No interactions are known with other medications.

Are you taking Campral along with other medications and have you recently done or is there a possibility that you will take other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines that you can obtain without a prescription.

What should you pay attention to with food, drink, and alcohol?

Food affects the amount of acamprosate absorbed in the body. However, Campral should be taken with meals because it is better tolerated then.

Simultaneous use of Campral and alcohol does not result in an interaction.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

The effect of Campral on pregnancy is not known. Therefore, Campral should only be used during pregnancy after careful consideration of the benefits and risks.

The effect of Campral when breastfeeding is not known, therefore Campral should not be used while breastfeeding.

So far, no harmful effects have been observed in animal studies. It is not known whether Campral affects fertility in humans.

Campral contains propylene glycol

This medicine contains 4.2 mg of propylene glycol per tablet.

Campral contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, meaning it is essentially 'sodium-free'.

3. How to take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Your doctor will prescribe the dosage. Follow your doctor's advice closely when taking Campral. Consult your doctor or pharmacist if in doubt. The usual dosage is:

For adults up to 60 kg, the dosage is 4 tablets of Campral per day. Take the tablets during meals as follows:

2 tablets in the morning, 1 tablet at noon, and 1 tablet in the evening.

For adults from 60 kg, the dosage is 6 tablets per day. Take the tablets during meals as follows: 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening.

In patients with moderate kidney problems, it may be necessary to adjust the dose. The starting dose is as follows:

1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening (during meals).

Discuss this with your doctor first.

Do not chew.

If you notice that Campral is too strong or not strong enough, consult your doctor or pharmacist.

The recommended duration of treatment is 1 year. Treatment with Campral should be started as soon as possible after the withdrawal period. If you do consume alcohol briefly, continue using Campral as usual.

Have you taken too much of this medicine?

If you have taken too much Campral, contact your doctor or pharmacist immediately.

Diarrhea may indicate an overdose.

Have you forgotten to take this medicine?

Do not take a double dose to make up for a forgotten dose, but take the next dose at the usual time.

If you stop taking this medicine

Always consult your doctor if you are considering stopping the use of Campral.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. Side effects can:

- be very common (in more than 1 in 10 patients);
- be common (in more than 1 in 100, but in less than 1 in 10 patients);
- be uncommon (in more than 1 in 1,000, but in less than 1 in 100 patients);
- be rare (in more than 1 in 10,000, but in less than 1 in 1,000 patients);
- very rarely occur (in less than 1 in 10,000 patients).

The following side effects are very common:

Diarrhea

The following side effects are common:

Abdominal pain, nausea, vomiting, flatulence, itching, rash with spots and bumps (maculopapular rash), sexual insensitivity (frigidity) or impotence, decreased libido

The following side effects are sometimes observed:

Increased libido

Very rarely occur:

Hypersensitivity reactions including rash with severe itching and formation of welts (hives or urticaria), sudden swelling in the skin and mucous membranes (e.g., throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema) or a strong drop in blood pressure, pallor, restlessness, weak rapid pulse, clammy skin, reduced consciousness due to a sudden strong vasodilation as a result of severe hypersensitivity to certain substances (anaphylactic reactions).

If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date. You can find it on the box and the blister after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is acamprosate.
- The other substances in this medicine are crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, polyacrylate resin, talc, and propylene glycol.

What does Campral look like and what is in a package?

Campral is a coated, gastro-resistant tablet. The tablets are white and round and are packaged in boxes with 7 blister strips (PVC/PVDC Aluminum) of 12 tablets each.

Marketing authorization holder

Merck BV

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Manufacturer

Merck Santé s.a.s.

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France

Registered under: RVG 18220

This leaflet was last approved in February 2021

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