

PART III: CONSUMER INFORMATION

PrCAMPRAL® Acamprosate Calcium Delayed-Release Tablets

This leaflet is part III of a three-part "Product Monograph" published when CAMPRAL® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CAMPRAL®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CAMPRAL® is used to help alcohol dependent people keep from drinking alcohol. It should be used as part of a complete treatment program that includes counselling. Before beginning this medication, you should no longer be drinking alcohol.

CAMPRAL® has not been shown to be effective if you are still drinking when you start taking it.

What it does:

CAMPRAL® is believed to work by restoring the natural balance of chemicals in the brain.

When it should not be used:

- If you are sensitive (allergic) to CAMPRAL®, or any component of this medication (see "What the nonmedicinal ingredients are" section).
- If you suffer from severe kidney problems.
- If you are breast-feeding.

What the medicinal ingredient is:

Acamprosate calcium

What the nonmedicinal ingredients are:

Anionic copolymer of methacrylic acid and acrylic acid ethyl ester, colloidal anhydrous silica, crospovidone, magnesium silicate, magnesium stearate, microcrystalline cellulose, propylene glycol, sodium starch glycolate and talc.

What dosage forms it comes in:

Each CAMPRAL® delayed-release tablet 333 mg is available as an enteric-coated, white, round-shaped tablet with "333" on one side. Tablets are supplied in blisters of 84 tablets.

WARNINGS AND PRECAUTIONS

If you develop any new or worsening mental health symptoms such as depression or thoughts of suicide while taking CAMPRAL® you should talk to your doctor or pharmacist immediately.

The use of CAMPRAL® does not eliminate or reduce the symptoms of alcohol withdrawal (the symptoms people experience when they stop drinking alcohol abruptly when they are dependent on alcohol).

CAMPRAL® therapy should be used as a part of a treatment program that includes counselling and support.

CAMPRAL® therapy should be continued as directed, even in the event of relapse (renewed drinking of alcohol) and any renewed drinking should be discussed with your doctor.

BEFORE you use CAMPRAL® talk to your doctor or pharmacist if:

- You are pregnant or likely to become pregnant.
- CAMPRAL® could be used during pregnancy if you can not abstain from alcohol without being treated with CAMPRAL®. CAMPRAL® does not prevent the harmful effect on fetus of alcohol intake.

Although in controlled studies CAMPRAL® has not been shown to impair coordination, certain drugs (e.g. sedatives, antidepressants) may impair judgment, thinking, or motor skills. Take precaution when operating hazardous machinery, including automobiles, until you are reasonably certain that CAMPRAL® therapy does not affect your ability to participate in such activities.

INTERACTIONS WITH THIS MEDICATION

CAMPRAL® has not been shown to interact significantly with other medications. If you are currently taking a medication, whether on prescription or otherwise, inform your doctor or pharmacist.

PROPER USE OF THIS MEDICATION

Usual dose:

The recommended dose of CAMPRAL® is two 333 mg tablets taken three times daily. CAMPRAL® should be swallowed whole, not crushed, chewed or split, and may be taken with or without food.

Treatment in patients with moderate kidney disease requires a dose reduction (one 333 mg tablet taken three times daily).

Never take more than the prescribed dose.

Lower dose may be prescribed temporarily for tolerability reasons.

Overdose:

Seek emergency medical attention. Symptoms of overdose may include diarrhea.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The side effects most often seen are gastrointestinal in nature, such as diarrhea, abdominal pain, gas and nausea. If you experience any of these effects, continue taking CAMPRAL® and talk to your doctor.

Other less common side effects may include:

- Rash, itching
- Weight gain/loss
- Change in sexual desire or ability

Check with you doctor or pharmacists if you experience any unexpected effects, or are concerned by the above side effects.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Rash or itching			√
	Thoughts or acts of self harm (suicide)		√	
Uncommon	Allergic reaction (Rash or itching, swelling, severe dizziness, trouble breathing)			√
	Joint pain			√

This is not a complete list of side effects. For any unexpected effects while taking CAMPRAL®, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15°C - 30°C).

Keep out of reach of children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about CAMPRAL®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website www.mylan.ca, or by calling 1-844 596-9526

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