

ACAMPROSATE MYLAN

acamprosate calcium

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ACAMPROSATE MYLAN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ACAMPROSATE MYLAN against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What ACAMPROSATE MYLAN is used for

ACAMPROSATE MYLAN 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. ACAMPROSATE MYLAN, 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.

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

ACAMPROSATE MYLAN is not recommended for use in children or elderly patients.

ACAMPROSATE MYLAN is available only with a doctor's prescription.

There is no evidence that ACAMPROSATE MYLAN is addictive.

Before you take ACAMPROSATE MYLAN

When you must not take it

Do not take ACAMPROSATE MYLAN if you have an allergy to:

- any medicine containing acamprosate calcium
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take ACAMPROSATE MYLAN if:

- you have kidney disease
- you have severe liver disease

Do not take this medicine if you are pregnant.

The safety of ACAMPROSATE MYLAN has not been established in pregnant women.

Do not take this medicine if you are breastfeeding.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

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

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

Tell your doctor if you have allergies 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 are pregnant or plan to become pregnant or breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

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

Some medicines and ACAMPROSATE MYLAN may interfere with each other.

How to take ACAMPROSATE MYLAN

Follow all directions given to you by your doctor or 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 for help.

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 with meals.

How to take it

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 a stomach upset.

How long to take it

ACAMPROSATE MYLAN is usually taken for one year.

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

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 medicine 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.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think

you or anyone else may have taken too much ACAMPROSATE MYLAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ACAMPROSATE MYLAN

Things you must do

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ACAMPROSATE MYLAN.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use ACAMPROSATE MYLAN to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Drinking alcohol while taking ACAMPROSATE MYLAN will not make you feel sick. However, you are advised not to drink alcohol at all during your treatment with ACAMPROSATE MYLAN. 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 ACAMPROSATE MYLAN.

This medicine helps most people with alcohol dependence, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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 side effects. You may not experience any of them.

Tell your doctor or pharmacist 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 people.

After using ACAMPROSATE MYLAN

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Do not store ACAMPROSATE MYLAN or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

Each pack contains 180 tablets.

Ingredients

The active ingredient in ACAMPROSATE MYLAN is acamprosate calcium.

Each 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.

Supplier

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration number:

AUST R 298641

This leaflet was prepared in March 2018.

acamprosate mylan_cmi\Mar18/00