

APO-Acamprosate

Contains the active ingredient acamprosate (as acamprosate calcium)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Acamprosate Enteric Coated Tablets. It contains the active ingredient acamprosate calcium.

It is used to treat 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, 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**

- kidney impairment
- severe liver problems.

- **You are pregnant.**

Acamprosate may affect your developing baby if you take it during pregnancy.

- **You are breastfeeding.**

Acamprosate may pass into human breast milk.

- **You are hypersensitive to, or have had an allergic reaction to, ac or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

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

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

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - liver disease.
 3. You plan to become pregnant. Do not take this medicine whilst pregnant.
 4. You plan to breastfeed. Do not take this medicine whilst breastfeeding.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with acamprosate, such as naltrexone.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

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

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The recommended dosages by patient weight are:

Over 60 kg:

2 tablets three times a day.

Under 60 kg:

2 tablets in the morning, 1 tablet at midday and 1 tablet at night.

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

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 stomach upset.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

This medicine should be taken with meals.

How long to take it for

This medicine is usually taken for one year.

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking acamprosate or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side

effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

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

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

Allergic reactions

If you think you are having an allergic reaction to acamprosate, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

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

- may have fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Acamprosate Enteric Coated Tablets looks like

333 mg enteric coated tablets:

White to off-white coloured, round-shaped, biconvex film-coated tablets engraved "APO" on one side and "300" on the other side.

Blister pack of 180 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each enteric coated tablet contains 333 mg of acamprosate calcium as the active ingredient.

It also contains the following inactive ingredients:

- Methylcellulose
- hyplose
- Crospovidone
- Magnesium Stearate

- Methacrylic Acid Copolymer
- Triethyl Citrate
- purified talc
- Sodium hydroxide.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Acamprosate 333 mg tablets (Blister Pack): AUST R 286652.

Sponsor

Apotex Pty Ltd

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