

ACAMPROSATE VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking ACAMPROSATE VIATRIS?

ACAMPROSATE VIATRIS contains the active ingredient acamprosate calcium. ACAMPROSATE VIATRIS is used in the treatment of alcohol dependence. It helps people who are dependent on alcohol to abstain from drinking alcoholic beverages.

For more information, see Section [1. Why am I taking ACAMPROSATE VIATRIS?](#) in the full CMI.

2. What should I know before I take ACAMPROSATE VIATRIS?

Do not take if you have ever had an allergic reaction to acamprosate calcium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take ACAMPROSATE VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ACAMPROSATE VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take ACAMPROSATE VIATRIS?

- 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.
- Swallow the tablets whole with a glass of water. Do not break, crush or chew the tablets.
- ACAMPROSATE VIATRIS is usually taken for one year. Continue taking your medicine for as long as your doctor tells you.

More instructions can be found in Section [4. How do I take ACAMPROSATE VIATRIS?](#) in the full CMI.

5. What should I know while taking ACAMPROSATE VIATRIS?

Things you should do	<ul style="list-style-type: none">• It is important to continue taking ACAMPROSATE VIATRIS even if you have a short relapse.• Remind any doctor, dentist or pharmacist you visit that you are taking ACAMPROSATE VIATRIS.• Keep all of your doctor's appointments so that your progress can be checked.• Call your doctor straight away if you become pregnant while taking ACAMPROSATE VIATRIS.
Things you should not do	<ul style="list-style-type: none">• Do not take ACAMPROSATE VIATRIS to treat any other complaints unless your doctor tells you to.• Do not give ACAMPROSATE VIATRIS 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.
Drinking alcohol	<ul style="list-style-type: none">• Drinking alcohol while taking ACAMPROSATE VIATRIS will not make you feel sick. However, you are advised not to drink alcohol at all during your treatment with ACAMPROSATE VIATRIS. Even if you only drink a little alcohol, you run the risk of making your treatment fail.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Keep your tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while taking ACAMPROSATE VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you: diarrhoea; nausea (feeling sick), vomiting, upset stomach; itching, skin rash; changes in sex drive.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ACAMPROSATE VIATRIS

Active ingredient(s): *acamprosate calcium*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ACAMPROSATE VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ACAMPROSATE VIATRIS.**

Where to find information in this leaflet:

1. [Why am I taking ACAMPROSATE VIATRIS?](#)
2. [What should I know before I take ACAMPROSATE VIATRIS?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take ACAMPROSATE VIATRIS?](#)
5. [What should I know while taking ACAMPROSATE VIATRIS?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking ACAMPROSATE VIATRIS?

ACAMPROSATE VIATRIS contains the active ingredient **acamprosate calcium**.

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

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

There is no evidence that ACAMPROSATE VIATRIS is addictive.

2. What should I know before I take ACAMPROSATE VIATRIS?

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

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

Warnings

Do not take ACAMPROSATE VIATRIS if:

- you are allergic to any medicine containing acamprosate calcium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine. 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
- you have kidney disease
- you have severe liver disease.

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

Check with your doctor if you:

- have allergies to any other medicines, foods, dyes or preservatives
- have any other health problems or medical conditions
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

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

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor can discuss with you the risks and benefits involved.

Do not take this medicine if you are breastfeeding.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with ACAMPROSATE VIATRIS and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ACAMPROSATE VIATRIS.

4. How do I take ACAMPROSATE VIATRIS?

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 ACAMPROSATE VIATRIS

- 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 VIATRIS is usually taken for one year.
- Continue taking your medicine for as long as your doctor tells you.

If you forget to take ACAMPROSATE VIATRIS

If you miss your dose at the usual time and 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 ACAMPROSATE VIATRIS

If you think that you or anyone else have taken too much ACAMPROSATE VIATRIS, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ACAMPROSATE VIATRIS?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking ACAMPROSATE VIATRIS.
- It is important to continue taking ACAMPROSATE VIATRIS 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 VIATRIS.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- become pregnant while taking ACAMPROSATE VIATRIS.

Things you should not do

- Do not take ACAMPROSATE VIATRIS to treat any other complaints unless your doctor tells you to.
- Do not give ACAMPROSATE VIATRIS 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.

Drinking alcohol

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

Looking after your medicine

- 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.
- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by this list of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• diarrhoea• nausea (feeling sick), vomiting, upset stomach• itching, skin rash• changes in sex drive	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ACAMPROSATE VIATRIS contains

Active ingredient (main ingredient)	acamprosate calcium 333 mg per enteric coated tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• crospovidone• microcrystalline cellulose• magnesium silicate dihydrate• sodium starch glycollate• colloidal anhydrous silica• magnesium stearate• purified talc• propylene glycol• EUDRAGIT L30D-55 (ARTG PI No: 3700)
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What ACAMPROSATE VIATRIS looks like

ACAMPROSATE VIATRIS 333 mg enteric coated tablet is a 10 mm round, white, coated tablet, debossed "333" on one side (AUST R 298641).

Available in blister packs of 180 tablets.

Who distributes ACAMPROSATE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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