

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Acamprosate 333 mg gastro-resistant tablets** acamprosate calcium

**Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Acamprosate is and what it is used for
2. What you need to know before you take Acamprosate
3. How to take Acamprosate
4. Possible side effects
5. How to store Acamprosate
6. Contents of the pack and other information

#### **1. What Acamprosate is and what it is used for**

Acamprosate is a medicine which acts on the central nervous system (the brain and the spinal cord). Acamprosate is used for the treatment of alcohol dependence. It helps to maintain abstinence in alcohol-dependent patients.

Acamprosate in combination with counselling will help you to not drink alcohol. It does this by acting on the chemical changes that have taken place in the brain during the years that you have been drinking alcohol. It does not prevent the harmful effects of continuous alcohol abuse.

#### **2. What you need to know before you take Acamprosate**

##### **Do not take Acamprosate:**

- if you are allergic to acamprosate or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.
- if you have reduced kidney function.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Acamprosate.

Acamprosate is not recommended for use:

- if you are a patient below the age 18 years or if you are above the age 65 years.
- if you suffer from severe liver disease.

If you drink too much alcohol, your body and in particular your nervous system adapt to the effects of alcohol. When you then suddenly stop drinking you may experience some unpleasant symptoms

known as alcohol withdrawal syndrome. You should take Acamprosate as soon as possible after the withdrawal period.

Because patients who suffer from alcohol dependence often also suffer from depression and are at risk of thinking about suicide, it is recommended that you be monitored for symptoms of depression and thoughts of committing suicide.

### **Other medicines and Acamprosate**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Acamprosate has often been given to patients together with other medicines that are used to treat alcohol withdrawal or maintain abstinence. So far, acamprosate does not seem to interfere with the effects of other medicines, however if you are prescribed diuretics (water tablets) talk to your doctor.

### **Acamprosate with alcohol**

Drinking alcohol while taking Acamprosate does not make you feel sick, however do not drink alcohol at all during your treatment with Acamprosate. Even if you drink a small amount of alcohol you run the risk of making your treatment fail and you may end up drinking heavily again.

### **Pregnancy and breast-feeding**

#### Pregnancy:

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Experience with treatment during pregnancy is limited. Pregnant women should therefore only use Acamprosate when a doctor has assessed that the benefit of treatment outweighs the possible risk to the foetus.

#### Breast-feeding:

If you are breastfeeding, do not take Acamprosate because it is not known whether this medicine passes into breast milk.

### **Driving and using machines**

Acamprosate has no influence on the ability to drive and use machines.

#### Acamprosate contains sodium

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

## **3. How to take Acamprosate**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### Dosage

*Adults within the age range 18-65 years:*

- If you weigh 60 kg or more, the recommended dose is 6 tablets a day: 2 tablets in the morning, 2 tablets at noon and 2 tablets in the evening with meals.

- If you weigh less than 60 kg, the recommended dose is 4 tablets a day: 2 in the morning, 1 at noon and 1 in the evening with meals.

#### Duration of treatment

It is recommended that you keep taking Acamprosate for one year.

#### Method of administration

Swallow this tablet whole. Do not chew or crush the tablet as this may damage the gastro-resistant coating.

#### **If you take more Acamprosate than you should**

If you take too many tablets, call your doctor or hospital casualty department immediately. You may experience symptoms of diarrhoea such as frequent loose or watery stools, abdominal cramps, stomach pains, fever, feeling sick and vomiting.

#### **If you forget to take Acamprosate**

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

#### **If you stop taking Acamprosate**

Talk to your doctor before you stop taking the tablets and follow their advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any of the following serious side effects, stop taking acamprosate and **contact your doctor immediately**:

**Very rare** (may affect up to 1 in 10 000 people)

- severe allergic reaction causing a rash, itching or hives (urticaria) on the skin, swelling of the face, lips, tongue or other parts of the body (angioedema) or shortness of breath, trouble breathing with rash, swelling, wheezing and feeling faint (anaphylaxis reaction)

**Other side effects include:**

**Very common** (may affect more than 1 in 10 people)

- diarrhoea

**Common** (may affect up to 1 in 10 people)

- stomach ache
- feeling sick (nausea)
- vomiting
- excessive gas in the stomach or bowel (flatulence)
- spotty red skin rash
- decreased sexual desire (libido)

**Uncommon** (may affect up to 1 in 100 people)

- increased sexual desire (libido)

**Not known** (frequency cannot be estimated from the available data)

- blistering rash characterised by patches of skin filled fluid (vesiculo-bullous eruptions)

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Acamprosate**

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Acamprosate contains**

The active substance is acamprosate calcium. Each gastro-resistant tablet contains 333 mg acamprosate calcium corresponding to 300 mg of acamprosate.

The other ingredients are glycerol dibehenate, microcrystalline cellulose, hypromellose, silica colloidal anhydrous and magnesium stearate. The coating includes hypromellose, methacrylic acid-ethyl acrylate copolymer, (1:1) dispersion 30% (contains sodium laurilsulfate, polysorbate 80), talc, propylene glycol.

### **What Acamprosate looks like and contents of the pack**

Acamprosate gastro-resistant tablets are white, round, biconvex, coated tablets plain on both sides and approximately 10 mm diameter.

Acamprosate is available in blister packs of 84, 168 and in a multipack of 168 comprising of 2 cartons, each containing 84 tablets or 504 comprising of 6 cartons, each containing 84 tablets.

Acamprosate is also available in HDPE bottle containing 250 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

### **Manufacturer**

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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