

Pathways Guidelines Development Subgroup

ACAMPROSATE FOR MAINTAINING ABSTINENCE IN ALCOHOL DEPENDENT ADULTS

INFORMATION FOR PRIMARY CARE



RAG List Status

Acamprosate is classified as a GREEN (in conjunction with specialist service) drug by the Greater Manchester Medicines Management Group.

Licensed Indications

Acamprosate is indicated as therapy to maintain abstinence in alcohol-dependent patients. It should be combined with counselling. Counselling and psychosocial support needs to be provided by the specialist service. It is also used off-label (unlicensed) to reduce consumption in patients who have not fully stopped drinking to reduce the risk of a lapse becoming a full relapse.

NICE Guidance

NICE Guideline 115 (Alcohol-use disorders) recommends the use of acamprosate in combination with an individual psychological intervention, after successful withdrawal from moderate to severe alcohol dependence.

When should GPs be asked to prescribe?

GP will only prescribe when:

- Patient has been identified as alcohol dependent/successfully withdrawn from alcohol and participating in an alcohol reduction program.
- GP asked to initiate treatment as appropriate by the specialist alcohol service.

GPs should not prescribe when:

- Patient is under the age of 18 years old.
- Patient not participating in an alcohol reduction program.
- If patient continues or starts drinking again the GP should discuss and seek advice from the specialist service.

Preparations available

Acamprosate calcium, 333mg, enteric-coated tablets (Campral EC®)
Generic Acamprosate 333mg Gastro-resistant tablets (Generics UK T/A Mylan)

Dosage and Administration

Adult >60kg: 666mg (2 tablets) three times daily.
Adult <60kg: 666mg mane, 333mg midday and 333mg night.
Acamprosate taken with food leads to a reduction in absorption and bioavailability.

Dose Modifications

Renal Impairment	Hepatic Impairment
No dose adjustment is recommended for patients with mild or moderate renal impairment	No dose adjustment is recommended for patients with mild or moderate hepatic impairment

Contraindications

- Established hypersensitivity to Acamprosate or any of the excipients in the preparation.
- Renal insufficiency (creatinine >120 mmol/l)
- Severe hepatic failure (Childs-Pugh classification C)
- Pregnancy (discuss risks in women of child bearing age)
- Breast-feeding
- Children <18 years old

Cautions

- The safety and efficacy of acamprosate has not been established in patients younger than 18 years or older than 65 years. Use is therefore not recommended for use in these populations.
- The interrelationship between alcohol dependence, depression and suicidality is well-recognised and complex, it is recommended that alcohol-dependent patients, including those treated with acamprosate, be monitored for such symptoms.

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What are the main side-effects?

Adverse event System – symptom/sign	Action to be taken Include whether drug should be stopped prior to contacting secondary care specialist
In up to 10% of patients diarrhoea may occur, less frequently nausea, vomiting or abdominal pain.	Generally self limiting and does not require cessation of the drug, If severe and persistent then withdraw medication.
Pruritus may occur and occasionally a maculopapular rash	Generally self limiting and does not require cessation of the drug, If severe and persistent then withdraw medication.
Fluctuation of libido	If severe and patient wishes discontinue.
Bullous rash (rare)	Discontinue, consider referral to dermatology

Drug Interactions

No significant interactions have been associated with the use of Acamprosate.
Concomitant intake of alcohol does not affect the pharmacokinetics of either agent.
Acamprosate can be used safely with benzodiazepines (e.g. as part of a detoxification).

Monitoring

Baseline urea and electrolytes and liver function tests (including gamma glutamyl transferase (GGT)) are recommended before commencing acamprosate.

Efficacy and side effects to be monitored monthly for the first 6 months (as per NICE), then 6-8 weekly.
Side-effects should be monitored by the GP.
Efficacy should be monitored by the specialist service in discussion with GP as necessary.

When should the drug be stopped?

If patient starts drinking again or if drinking persists 4-6 weeks after initiating acamprosate the GP should discuss and seek advice from the specialist service.
Treatment to be terminated by the GP in consultation with the specialist service providing psychosocial support.
Treatment should be continued for 6-12 months. Terminate after 12 months.
Treatment should be discontinued in the event of a full relapse, if there is lack of efficacy, or intolerable side effects occur.

References

Acamprostate (Campral EC®) Summary of Product Characteristics May 2015
<https://www.medicines.org.uk/emc/product/986>
NICE CG 115