560FM.1 ACAMPROSATE FOR USE IN TREATMENT OF ALCOHOL DEPENDENCY IN ADULTS 18 YEARS AND OVER
Amber Initiation Guideline

This guideline provides prescribing and monitoring guidance for acamprosate therapy. It should be read in conjunction with the Summary of Product Characteristics (SPC) available on www.medicines.org.uk/emc and the British National Formulary (BNF).

BACKGROUND FOR USE

Acamprosate is an established treatment used in the treatment of alcohol cravings after the patient has gained abstinence from alcohol. It is typically prescribed for 6 months up to 18 months or as long as the patient benefits after the patient has stopped misusing alcohol (CG115 NICE Guidance).
It is an anticraving drug, which belongs to the group of Gamma-Amino-Butyric-Acid analogues and derivatives.

SUPPORTING INFORMATION

Acamprosate is an established drug with a known side effect profile. It is used as first line therapy for the treatment of alcohol abstinence.

CONTRAINDICATIONS

- No known contraindications.

PRECAUTIONS

- Avoid in pregnancy and breastfeeding unless potential benefit outweighs risk.
- Avoid in patients under the age of 18 and above the age of 65.
- Avoid if serum-creatinine is greater than 120 micromol/litre.
- Avoid in severe hepatic impairment.
- Continued alcohol misuse (risk of treatment failure).

DOSAGE

- For adult 18 - 65 years (body weight up to 60 kg): two tablets (666 mg) in the morning at breakfast and one tablet (333 mg) at midday and night.
- For adult 18 - 65 years body weight 60 kg and above: two tablets (666 mg) three times a day.

TIME TO RESPONSE

- Within seven days.

PRE-TREATMENT ASSESSMENT BY ONE RECOVERY BUCKS (ORB)

- Urea + electrolytes (U+E) and liver function test (LFT) needed within 6 weeks before prescribing the medication by in-house phlebotomist and results are sent through to GP surgery (ORB do not have access to OrderComms (ICE)).
- Prior to request for acamprosate prescribing to be shared with the patient's general practitioner (GP), the patient will be abstinent of alcohol and have a care plan and details of post treatment psychosocial interventions at ORB in place.
- ORB to ensure that alcohol is not consumed for at least 24 hours before treatment is initiated by use of breathalyser.
- This treatment package will be communicated electronically to the patient's GP via secure **nhs.net** email.

RESPONSIBILITES

ORB

- A comprehensive assessment by the recovery worker and ORB doctor or non-medical prescriber (NMP) to be done initially to establish diagnosis and develop a care plan. Ensure the plan contains contact details for care coordinator/key worker and specialist prescriber.
- Organise blood tests prior to treatment, LFTs and U&Es. The results will be recorded in GP patient notes and ORB are responsible for reviewing the results. (ORB do not have access to ICE hence the results are sent to GP.)
- Initiate treatment and prescribe the first 28 days of treatment.
- Ensure the patient understands the nature and complications of drug therapy and their role in reporting adverse effects promptly and complies with attending regular appointments.
- Provide copy of patient information leaflet and drug monitoring card where appropriate.
- Send secure email to the GP requesting the continuation of prescribing of acamprosate.
- ORB will email GP monthly for first 6 months to confirm compliance with attending appointments, and to confirm that the GP can continue to prescribe the next monthly script of acamprosate.
- At 6 months ORB will inform GP of the care plan. This may be:
  - The patient's treatment is stopped as no further benefit identified.
  - The patient is assessed by ORB as compliant and is safe to be discharged from ORB, treatment is recommended to be continued to be prescribed by the GP for a maximum of a further 12 months (18 months in total). No ongoing monitoring by the GP is required. The GP will add the recommended stop date to the prescription. If the patient or GP has any concerns ORB to be contacted for further advice. If the patient or GP believes there may be benefit in continuing treatment after 18 months they can contact ORB for advice on further prescribing.
  - The patient will continue to be seen less frequently by ORB, treatment is recommended to be continued to be prescribed by the GP for a maximum of a further 12 months (18 months in total). If there are any changes to the patient's alcohol use, or missed clinic appointments ORB will inform the GP and recommend any changes in treatment. If the patient or GP believes there may be benefit in continuing treatment after 18 months they can contact ORB for advice on further prescribing.
- ORB will be available to give advice to the GP and patient throughout treatment.
- Ensure patient is fully informed about their treatment including discussing with them any plans of pregnancy.
- The GP will be informed if it is known that the service user is pregnant prior to prescribing of acamprosate being agreed.
- Email a copy of the care plan to GP.
- Discuss appropriate lifestyle issues with the patient if appropriate.
- Monitor for response and adverse drug reactions; to report adverse drug reactions to Medicines and Healthcare Products Regulatory Agency (MHRA) and GP.
- Inform GP of any concurrent therapy as this may interact with any other medicine patient is prescribed by GP.

GP

- Email ORB via secure nhs.net email to acknowledge the continued prescribing of acamprosate within 14 days of receipt of request.
- Notify ORB to any changes in patient's medical condition, any adverse drug reactions, or failure to attend appointments.
- At each monthly review for the first six months, GP to review ORB key workers email and check that the patient continues to be compliant with the information from ORB.

- GP to continue to prescribe for at least 6 months but up to 18 months if it benefits the patient and patient wants to continue taking medication. The GP will receive a monthly email confirmation from ORB that the patient is compliant with the programme for the first six months.
- Prescribe thiamine 100 mg tablets (vitamin B1), one tablet three times a day.
- Stop prescribing if ORB notify GP practice that patient is non compliant or not attending ORB monthly review.

Patient

- Agree to treatment and monitoring after making an informed decision.
- Attend for blood tests and monitoring when required.
- Report any side effects to the GP or a member of the specialist team.
- Attend education session if offered.
- Attend the monthly follow up by ORB and any other support recommended by ORB.
- Maintain abstinence from alcohol.
- Immediately inform ORB or GP if becomes pregnant.

This guideline provides prescribing and monitoring guidance for acamprosate therapy in adults.

Monitoring by ORB

- Service users taking acamprosate should stay under supervision, at least monthly, for 6 months, and at reduced but regular intervals if the drug is continued after 6 months.
- Routine blood tests are not required, but consider them to monitor for recovery of liver function and as a motivational aid for service users to show improvement. These would be initiated by ORB.
- ORB will continue to work with those prescribed acamprosate. As part of this engagement, ORB will randomly request the patient to be breathalysed. The results of these are to be shared with the patient's GP.
- If the patient returns to persistent drinking 4 – 6 weeks after commencing treatment the medication should be **stopped.**

Supporting Information

- ORB will supply the first 28 days of acamprosate to the patient.
- ORB will email attendance at psychosocial interventions monthly to the patient's GP so continuation of prescriptions for the patient in aftercare can be ensured. If patient stops attending psychosocial interventions GP will be advised to stop prescribing of the medication.

SIDE EFFECTS AND ACTIONS TO BE TAKEN

Common Side Effects	Action
• Abdominal pain	Often transient. Usually resolves with time.
• Diarrhoea	Often transient. Usually resolves with time.
• Flatulence	Often transient. Usually resolves with time.
• Nausea	
• Sexual dysfunction	Often transient. If possible continue after reassuring patient.
• Pruritus	Stop if significant and discuss with ORB
• Vomiting	If possible continue with antiemetic. Stop if significant and discuss with ORB.
Very Rare	
• Angiooedema	Stop and inform ORB
• Urticaria	Stop and inform ORB
• Hypersensitivity reaction	Stop and inform ORB

DRUG INTERACTIONS (REFER TO BNF AND SPC)

NONE in the BNF.

BACK-UP INFORMATION/ADVICE

CONTACT DETAILS	High Wycombe	Aylesbury
ORB	High Wycombe – 0300 772 9672 option 2 Secure email – OneRecovery.Bucks@nhs.net	Aylesbury – 0300 772 9672 option 1 Secure email – OneRecovery.Bucks@nhs.net

REFERENCES

1) BNF Substance Misuse Section 8.1
2) NICE guidance alcohol misuse prescribing: https://www.nice.org.uk/guidance/cg115
3) BNF acamprosate: https://bnf.nice.org.uk/drug/acamprosate-calcium.html
4) NICE guidance drug misuse and psychosocial interventions https://nice.org.uk/guidance/cg51

See also:

Guideline 561FM Naltrexone for use in Treatment of Alcohol Dependency in Adults 18 Years and Over

Guideline 562FM Disulfiram for use in Treatment of Alcohol Dependency in Adults 18 Years and Over

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CONFIDENTIAL

Shared Care Agreement Letter for Amber Initiation drugs

Dear Doctor,
Re: ***Patient name, DOB***
Address

Your patient has been established on the below treatment and is stable.
The patient has received a full explanation and written information about the benefits and potential side effects of the treatment, an explanation of blood tests, monitoring requirements and the relevant Telephone Helpline details.
The patient understands the need for attending appointments for monitoring and contacting healthcare professionals in case of side effects.

GP action required:	Please confirm the acceptance of shared care prescribing and monitoring by email to: onerecovery.bucks@nhs.net If you are unable to undertake shared care, we would appreciate understanding why. Please specify the reason below and return the form to the email address above.

Shared care specialist at ORB:
Shared care drug: Click to choose a drug.
(Full SCP available on DXS, dose will be confirmed by the latest clinic letter)
Formulary site: www.bucksformulary.nhs.uk/docs/sc/
Indication (please state)**:**

Date treatment commenced: Click to enter date.
Estimated date of the prescribing to be continued by GP: Click to enter date.