

Amber with Guidance (Amber-G) = To be recommended or initiated by a specialist* with follow up prescribing and monitoring by primary care clinicians.

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Acamprosate calcium

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF (<https://www.medicinescomplete.com/#/>) and the SPC (<https://www.medicines.org.uk/emc/>) remain authoritative.

Background Information	Acamprosate is thought to reduce drinking by modulating the brain glutamate function implicated in withdrawal symptoms. The response to this in vivo is that it suppresses the urge to drink in response to learned cues. It is therefore often referred to as the “anti-craving” drug. It is licensed for use in maintaining abstinence in alcohol dependent patients. It is most effective when prescribed as part of a psychosocial treatment package.
BNF therapeutic class	4.10. Drugs used in substance dependence https://bnf.nice.org.uk/treatment-summaries/alcohol-dependence/
Indication	<ul style="list-style-type: none"> Acamprosate is indicated as therapy to maintain abstinence in alcohol-dependent patients aged 18-65. It should be combined with counselling. Treatment compliant with <i>NICE Alcohol-use disorders: diagnosis and management of harmful drinking (high-risk drinking) and alcohol dependence</i>
Dosage and administration	<ul style="list-style-type: none"> Route of administration: Gastro-resistant tablets to be taken orally Duration: Acamprosate is usually prescribed for up to 6 months, or longer for those benefiting from it. The manufacturers recommend a treatment period of one year. However, if the patient is benefitting from the drug this may be continued as an “off-label” indication. Dose is dependent on patient’s weight: Patients >60kg should take 333mg x 2, three times a day (total 6 tablets) Patients < 60kg should take 333mg x 4 tablets per day divided throughout the day; total 4 tablets divided into three doses with meals (2 tablets in the morning, 1 tablet at noon and 1 at night) Stopping treatment: The treatment can be stopped abruptly although some patients prefer to reduce slowly as it gives them more confidence (expert-opinion). If a patient has a lapse, it may be worth continuing the treatment for a while (e.g., 4 - 6 weeks) as they may re-achieve abstinence. If it is clear the patient is not going to re-achieve abstinence the acamprosate should be withdrawn. Consider stopping prescribing acamprosate after 4-6 weeks if the person is continuing to drink alcohol and has experienced no reduced drinking days and alcohol consumption. Products and strengths available: Acamprosate 333mg gastro-resistant tablets, Campral® EC 333mg tablets
Cautions and Contraindications	<p>Cautions:</p> <ul style="list-style-type: none"> Continued alcohol use Under 18 or >65 Childs-Pugh C (Severe liver insufficiency) <p>Contraindications:</p> <ul style="list-style-type: none"> Hypersensitivity to the active substance or to any of the excipients Renal impairment – avoid if serum creatinine greater than 120 micromol/litre Breastfeeding (see below)

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Pregnancy and breast feeding	Pregnancy: Manufacturer advises avoid unless potential benefit outweighs risk. Breast feeding: Avoid - contraindicated																
Adverse Drug Reactions	<ul style="list-style-type: none"> • These are usually mild and transient. The most common are gastro-intestinal symptoms. • The most common adverse effects are listed here – please refer to the SPC for full details. <table border="1" data-bbox="411 412 1412 848"> <thead> <tr> <th data-bbox="411 412 914 443">Side Effect</th> <th data-bbox="922 412 1412 443">Suggested Action</th> </tr> </thead> <tbody> <tr> <td data-bbox="411 443 914 533">Diarrhoea</td> <td data-bbox="922 443 1412 533">Keep hydrated If severe discuss and consider discontinuation</td> </tr> <tr> <td data-bbox="411 533 914 658">Headaches</td> <td data-bbox="922 533 1412 658">Try paracetamol. Your pharmacist will be able to advise if this is safe to take with any other medicines you may be taking.</td> </tr> <tr> <td data-bbox="411 658 914 723">Stomach pain (including nausea/vomiting, flatulence)</td> <td data-bbox="922 658 1412 723">Tablets to be taken with or after food. Discuss with patient</td> </tr> <tr> <td data-bbox="411 723 914 754">Sexual dysfunction</td> <td data-bbox="922 723 1412 754">Discuss with patient</td> </tr> <tr> <td data-bbox="411 754 914 786">Skin rash/pruritus</td> <td data-bbox="922 754 1412 786">Discontinue until seen by a doctor</td> </tr> <tr> <td data-bbox="411 786 914 848">Allergy (difficulty breathing or being wheezy)</td> <td data-bbox="922 786 1412 848">Discontinue until seen by a doctor or emergency department</td> </tr> </tbody> </table> <ul style="list-style-type: none"> • Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme: www.mhra.gov.uk/yellowcard 			Side Effect	Suggested Action	Diarrhoea	Keep hydrated If severe discuss and consider discontinuation	Headaches	Try paracetamol. Your pharmacist will be able to advise if this is safe to take with any other medicines you may be taking.	Stomach pain (including nausea/vomiting, flatulence)	Tablets to be taken with or after food. Discuss with patient	Sexual dysfunction	Discuss with patient	Skin rash/pruritus	Discontinue until seen by a doctor	Allergy (difficulty breathing or being wheezy)	Discontinue until seen by a doctor or emergency department
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Monitoring	<ul style="list-style-type: none"> • Initiation should be by specialist services (Substance Misuse Team or Shared Care GP practices) and baseline bloods should include hepatic and renal function. <table border="1" data-bbox="403 1122 1420 2049"> <thead> <tr> <th data-bbox="403 1122 683 1160">Monitoring</th> <th data-bbox="691 1122 970 1160">Frequency</th> <th data-bbox="978 1122 1257 1160">Results and action</th> <th data-bbox="1265 1122 1420 1160">By whom</th> </tr> </thead> <tbody> <tr> <td data-bbox="403 1167 683 2049"> LFT U&Es Weight </td> <td data-bbox="691 1167 970 2049"> NICE recommend that blood tests should not be used routinely but they could be considered to monitor for recovery of liver function and as a motivational aid for people who use our services to show improvement (NICE, 2011) Due to contraindication status if creatinine level > 120 micromol/L and caution in severe liver insufficiency U&Es and LFTS should be checked annually. Weight change should be monitored routinely (especially </td> <td data-bbox="978 1167 1257 2049"> <ul style="list-style-type: none"> • Dose should be reduced to 1332mg/day if the patient weighs less than 60KG • Acamprosate is contraindicated if creatinine >120 micromol/L – do not prescribe or discontinue if prescribed (SPC, 2020) • The safety and efficacy of acamprosate has not been established in patients with severe liver insufficiency (Childs-Pugh C) – review benefits vs. risks if liver function compromised (SPC, 2020) </td> <td data-bbox="1265 1167 1420 2049">GP</td> </tr> </tbody> </table>			Monitoring	Frequency	Results and action	By whom	LFT U&Es Weight	NICE recommend that blood tests should not be used routinely but they could be considered to monitor for recovery of liver function and as a motivational aid for people who use our services to show improvement (NICE, 2011) Due to contraindication status if creatinine level > 120 micromol/L and caution in severe liver insufficiency U&Es and LFTS should be checked annually. Weight change should be monitored routinely (especially	<ul style="list-style-type: none"> • Dose should be reduced to 1332mg/day if the patient weighs less than 60KG • Acamprosate is contraindicated if creatinine >120 micromol/L – do not prescribe or discontinue if prescribed (SPC, 2020) • The safety and efficacy of acamprosate has not been established in patients with severe liver insufficiency (Childs-Pugh C) – review benefits vs. risks if liver function compromised (SPC, 2020) 	GP						
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		for patients with body weight around 60kg).		
	<ul style="list-style-type: none"> Patients should be monitored for abstinence at least monthly for 6 months, less frequently if treatment continued after 6 months. <p>Because 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.</p>			
Interactions	None reported. Acamprosate does not interact with alcohol.			
Additional information	<ul style="list-style-type: none"> Certificate in the Management of Alcohol Problems in Primary Care (RCGP Accredited) SLD Training Acamprosate has no influence on the ability to drive and use machines 			
Ordering information	<ul style="list-style-type: none"> Not applicable – supplied via FP10 through community pharmacies 			

Contact names and details

Contact Details	Telephone number	Email
Dr Fleur Ashby Consultant Clinical Director, Barnsley Recovery Steps	01226 779066	Amanda.Ashby@humankindcharity.org.uk
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- <https://humankindcharity.org.uk/service/barnsley-recovery-steps/>

Equality and diversity

- No details to be added with regards to acamprosate prescribing

References

- British National Formulary. Available at: <https://bnf.nice.org.uk/drugs/acamprosate-calcium/>
- Acamprosate (Campral®). Summary of Product Characteristics. June 2020. Available at: Campral® <https://www.medicines.org.uk/emc/product/986> and Acamprosate calcium: <https://www.medicines.org.uk/emc/product/2729/smpc#gref>
- Alcohol - Use Disorders. Diagnosis, assessment and management of harmful drinking and alcohol dependence. NICE Clinical Guideline 115. February 2011. Available at: <http://guidance.nice.org.uk/CG115>
- NICE Prescribing information for Acamprosate (Alcohol- problem drinking) <https://cks.nice.org.uk/topics/alcohol-problem-drinking/prescribing-information/acamprosate/#:~:text=Stop%20acamprosate%20if%20drinking%20persists,function%20and%20may%20aid%20motivation>
- Choice and Medication website (information about mental health conditions, treatments and medications). Available at: <https://www.choiceandmedication.org/humankind/generate/pillacamprosateuk.pdf>
- <https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf>

Development Process

This guidance has been produced by Dr Fleur Ashby following an AMBER-G classification status of Acamprosate calcium by the Barnsley Area Prescribing Committee. This guideline was ratified by the Area Prescribing Committee on 14th February 2024.