

ACAMPROSATE CALCIUM (Campral EC) for alcohol abstinence

ESCA: Adjunct in the treatment of chronic alcohol dependence (under medical supervision)
in adults (18 to 65 Years)

(For patients seen by/referred to the Derbyshire Recovery partnership)

1. REFERRAL CRITERIA

- Alcohol dependence confirmed
- Suitability for drug treatment
- Motivation to remain abstinent assessed
- No contraindications to treatment. Any cautions taken into account.
- Provide evidence via a breathalyser of abstinence for a minimum of 24 hours prior to treatment commencing
- Appropriate preferred support/supervisory network in place for Patient
- Possess an agreed recovery plan
- Condition is stable /predictable
- Effective monitoring is established

2. PRINCIPLES FOR THE SHARING OF CARE

- This shared care agreement outlines ways in which the responsibilities for managing the prescribing are shared between the specialist services and general practitioners (GP) where shared care provides an optimal solution for the patient.
- GPs are invited to participate and if not confident to undertake these responsibilities, then he/she is under no obligation to accept shared care.
- Where shared care is not accepted total clinical responsibility for the patient for the diagnosed condition and on-going supply of medication remains with the specialist.
- Sharing care assumes close communication between the specialist and GP therefore a specialist asks the GP to prescribe this drug, the GP should reply to the request as soon as practicable.
- Sharing care assumes communication between the specialist, GP and Patient therefore the process should be explained to the patient by the specialist initiating treatment and they are in agreement.
- The practitioner who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

3. AREAS OF RESPONSIBILITY

GP responsibilities	Specialist responsibilities
<ol style="list-style-type: none"> 1. See section 5.vi for GP monitoring requirements 2. To assess and monitor the patients physical health prior to, and during treatment once accepted into shared care 3. To reply to the request for shared care as soon as practicable 4. To continue the prescribing (normally for a maximum 12 months) continued only after liaison with specialist 5. To monitor the alcohol consumption and general health on a regular basis 6. To promote patient compliance 7. Ensure patient awareness of recovery support services available from alcohol services and/or GP support during the prescribing period. 8. To refer back to the specialist in the event of a relapse to drinking, or concerns over patient compliance 9. To report to and seek advice from the specialist on any aspects of patient care that is a concern and may affect treatment 10. To report any adverse effects to the referring specialist and MHRA yellow card scheme. 11. Stop treatment on the advice of the specialist staff or immediately if urgent need to stop treatment arises 	<ol style="list-style-type: none"> 1. To carry out a full holistic review and assessment of the patients suitability for treatment prior to prescribing 2. To be satisfied the patient is alcohol dependent 3. To arrange for a physical assessment to be carried out by the GP, to discuss the results and record this in the patients notes prior to prescribing 4. To discuss the risk/benefits of treatment with the patient and the need to avoid alcohol or products containing alcohol (including external products) 5. Encourage the patient to be alcohol free for 24 hours prior to commencement of treatment achieved through drink down 6. To stabilise the patient on treatment 7. To monitor for initially first 3 months with a view to continue or discontinue treatment 8. To ensure the patient is abstinent from alcohol 9. To agree the recovery plan with the patient 10. The GP is informed of commencement of medication as per shared care agreement. 11. To continue to prescribe until GP has arranged to take over prescribing 12. On request for shared care and transfer of prescribing, to supply four weeks maintenance therapy to allow GP handover 13. To encourage local arrangements to be made to support administration preferably by a carer or relative 14. To keep the GP informed of the patients progress and communicate when to continue treatment 15. To advise the GP when the treatment should be discontinued 16. To ensure a mechanism is in place to receive rapid referral of a patient from the GP if required if the patient deteriorates 17. To report any adverse effects to the MHRA yellow card scheme, and to inform the GP 18. To ensure that clear communication and support is in place for the GPs to obtain if required

Patient responsibilities

- To be alcohol free for 24 hours prior to commencement of treatment with the specialist
- To report to the specialist prescriber or GP if he/she does not understand the treatment clearly
- To maintain contact and engagement with services, as per the recovery plan, to enable them to work towards their recovery goals and overcome alcohol dependence
- To attend GP and other follow up appointments as scheduled
- To share any concerns in relation to treatment
- To seek medical assistance if he/she experiences an adverse reaction or side effect
- To report any adverse effects or warning symptoms to the specialist prescriber or GP

4. COMMUNICATION AND SUPPORT

<p>DHCFT Derbyshire Recovery Partnership www.derbyshirerecoverypartnership.co.uk</p>	<p>Out of hours contacts and procedures: Attend GP out of Hours or contact 111</p>
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<p>42 St Marys Gat, Chesterfield S41 7TH tel 0300 123 1201</p> <p>The Mews, 7 Church Street. Ripley DE5 3BU tel 01773 744594</p> <p>Erewash House, Station Rd., Ilkeston tel. 01159 309442</p> <p>Bankgate, Unit 13-15 Rinkway Ind Estate, Rink Drive, Swadlincote DE11 8JU tel. 0300 790 0263</p>	
<p>Specialist support/resources available to GP including patient information.</p> <p>Patient leaflets and treatment cards are available from the manufacturer. Downloadable patient information : http://www.medicines.org.uk</p> <p>GPs can liaise with the specialist alcohol services for any information or advice regarding disulfiram.</p>	

5. CLINICAL INFORMATION

i. Prescribed indications	Acamprosate is licenced for the maintenance of abstinence in alcohol dependence combined with counselling
ii. Therapeutic summary	Acamprosate is a synthetic taurine analogue, which acts as a functional glutamatergic NDMA antagonist and also increases GABAergic function.
iii. Dose & Route of administration	<p>Adults Weighting:</p> <p>< 60 kg 666mg (2 tablets) at breakfast, 333mg (1 tablet) at midday and 333mg (1 tablet) at night with meals</p> <p>> 60 kg 666mg (2 tablets) three times a day with meals Initiate as soon as possible after abstinence.</p> <p>Acamprosate should not be administered to children or the elderly</p>
iv. Duration of treatment	Recommended treatment period is 12 months and continued longer only following liaison with community alcohol teams.
v. Adverse effects	<p>Diarrhoea, nausea, vomiting, abdominal pain, flatulence, pruritus, rashes and fluctuating libido are possible.</p> <p>Should not impair ability to drive or operate machinery.</p> <p>For full information consult SPC</p>
vi. Monitoring Requirements	<p>Specialist service: Monitoring by the specialist for the initial first 3 months with a review to determine whether to continue or discontinue treatment at 12 months</p> <p>GP: To monitor the alcohol consumption and general health on a regular basis</p>
vii. Clinically relevant drug interactions	The concomitant intake of alcohol and Acamprosate does not affect the pharmacokinetics of either alcohol or Acamprosate. Administering Acamprosate with food diminishes the bioavailability of the drug compared with its administration in the fasting state. Pharmacokinetic studies have been completed and show no interactions between Acamprosate and diazepam, disulfiram or imipramine. There is no information available on the concomitant administration of Acamprosate with diuretics

<p>viii. Contra-indications</p> <p>ix. Cautions</p>	<p>In Patients with a known hypersensitivity to the drug or excipients In cases of renal insufficiency (serum creatinine >120 micromol/L) In cases with severe hepatic failure (Childs - Pugh Classification C)</p> <p>Pregnancy: Not recommended – inadequate data</p> <p>Lactation: Contraindication</p> <p>Acamprosate does not prevent the harmful effects of continuous alcohol misuse. Continued alcohol abuse negates the therapeutic benefit, therefore acamprosate treatment should only be initiated after weaning therapy, once the patient is abstinent from alcohol. Due to the well-recognised and complex link between alcohol dependence, depression and suicidality it is recommended that alcohol dependent patients, including those treated with acamprosate be monitored for such symptoms.</p>
<p>x. Supply of ancillary equipment eg. syringe drivers, tubing</p>	<p>Nil</p>
<p>xi. Prepared by</p>	<p>Specialist Alcohol Nurse Practitioners, Derbyshire Recovery Partnership DHCFT DCHFT Drug and Alcohol Advisory Group</p>

This does not replace the SPC, which should be read in conjunction with it.

Date prepared: January 2013 **Date reviewed:** October 2019

Next Review date: September 2022

References:

www.BNF.org.uk

Pennine Care shared care agreement

Summary of Product Characteristics Acamprosate: Accessed July 2017:

<https://www.medicines.org.uk/emc/medicine/33578>

NICE Clinical Guideline 115 (2011) Alcohol Use Disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence. www.nice.org.uk

Department of Health (2006) Models of care for alcohol Misusers (MoCAM)

Sample transfer letter

Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL

«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_ADDRESS_3»
«GP_ADDRESS_4»
«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_ADDRESS_3»
«CURRENT_ADDRESS_4» «CURRENT_POSTCODE»

Your patient was seen on {Insert date} with a diagnosis of {Insert diagnosis}. I have initiated the following medication {Insert drug name} and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

Dose Regimen	Date {Insert medicine name} started	Date for GP to start prescribing {Insert medicine name} from
The baseline test results are (if applicable):		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
<i>The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:</i>	
<i>Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory</i>	Yes / No
<i>The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care</i>	Yes / No
<i>The risks and benefits of treatment have been explained to the patient</i>	Yes / No
<i>The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist</i>	Yes / No

<i>have been explained and agreed</i>	
<i>The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments</i>	Yes / No
<i>I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)</i>	Yes / No
<i>I have included with the letter copies of the information the patient has received</i>	Yes / No
<i>I have provided the patient with sufficient medication to last until</i>	
<i>I have arranged a follow up with this patient in the following timescale</i>	

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

{Consultant name}

GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

		Tick which apply
1.	<p>The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care</p> <p>As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because <i>[insert reason]</i>. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.</p> <p>I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.</p>	
2.	<p>The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement</p> <p>As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.</p> <p>Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you</p>	
3.	<p>A minimum duration of supply by the initiating clinician</p> <p>As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</p>	
4.	<p>Initiation and optimisation by the initiating specialist</p> <p>As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</p>	
5.	<p>Shared Care Protocol not received</p> <p>As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed.</p> <p>For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</p>	

6.	Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)	
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Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to:

1. The specialist/consultant requesting shared care
2. **AN ANONYMISED COPY OF THIS FORM ONLY** to the Medicines Management and Clinical Policies and Decisions Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: ddccg.medicinesmanagement@nhs.net

(Sending a copy of this form to the Medicines Management and Clinical Policies and Decisions Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).