

SHARED CARE GUIDELINE

Title: Prescribing and monitoring of acamprosate in the treatment of alcohol dependence

Scope:

Pennine Care NHS Foundation Trust
To support an individualised care pathway where this has been previously agreed with the GP only.

Version:

Version 2

Issue date:

24 February 2014

Replaces:

Version 1

Author(s)/Originator(s)

Pennine Care NHS Foundation Trust

To be read in conjunction with the following documents:

MM0086 Community Alcohol Detoxification Guidelines

British National Formulary (BNF) 65 Mar-Sep 2013

NICE Clinical Guideline CG 115 Alcohol-use disorders February 2011 www.nice.org.uk

Summary of Product Characteristics Campral
<http://www.medicines.org.uk/emc/medicine/1042/SP/C/Campral+EC>

Authorised by:

Drugs and Therapeutics Committee, Pennine Care NHS Foundation Trust

Date authorised:

20 December 2013

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20 December 2016

1. Introduction

Acamprosate (Campral®) is licensed as therapy to maintain abstinence in alcohol-dependent patients. [1]

It has a chemical structure similar to that of amino acid neuromediators, such as gamma amino butyric acid (GABA), and may act by stimulating GABAergic inhibitory neurotransmission, and antagonising excitatory amino acids, particularly glutamate. [1]

NICE Guideline 115 (Alcohol-use disorders) [2] recommends the use of acamprosate in combination with an individual psychological intervention, after successful withdrawal from moderate to severe alcohol dependence

2. Scope

Pennine Care NHS Foundation Trust

3. Clinical Condition being treated

Acamprosate (Campral®) is licensed as therapy to maintain abstinence in alcohol-dependent patients. [1]

It is used primarily to reduce the risk of relapsing into heavy drinking – though it may also attenuate the level of drinking if a relapse occurs.

It should be initiated as soon as possible after abstinence has been achieved. The treatment effect is most pronounced at 6 months, although it remains significant up to 12 months. [3] The recommended treatment period is 12 months. [1]

Treatment should be maintained if the patient has a temporary relapse, but stopped if the patient returns to regular or excessive drinking that persists 4-6 weeks after starting treatment. [4]

Acamprosate does not constitute treatment for the symptoms of alcohol withdrawal.

Acamprosate does not prevent the harmful effects of continuous alcohol abuse.

4. Product information and treatment regimen to be used

Acamprosate (Campral®) is presented as 333mg enteric coated tablets.

Dose: Adults aged 18-65 years of over 60kg body weight, two tablets (666mg) three times daily with food.

Adults aged 18-65 years of under 60kg body weight, two tablets (666mg) at breakfast, and one tablet (333mg) at midday and night, with food [4]

Acamprosate should be avoided in severe hepatic impairment, and in renal impairment if the serum creatinine level is greater than 120 micromol/litre.

Acamprosate is not effective in all patients, so efficacy should be regularly assessed. [4]

NICE guidelines [2] recommend that patients taking acamprosate are monitored every month for the first 6 months of treatment, and then less frequently if the treatment continues beyond that. Reviews should include medication compliance, level of alcohol consumption (if any), any relevant health problems, and the patient's view of the effectiveness of the medication.

Within Pennine Care, acamprosate may be initiated by a consultant psychiatrist's team working within either the specialist Drug and Alcohol Service (DAS), or in general psychiatry. It may also be initiated by a General Practitioner with a Special Interest (GPwSI) working within the national Enhanced Guidelines for Alcohol. Otherwise a GP may initiate on the advice of the above teams where the secondary care service is not commissioned to initiate treatment.

Acamprosate may also be initiated in a tertiary service detoxification unit and this service will liaise with Pennine Care NHS Foundation Trust and the patients GP.

5. Regimen Management

Aspects of care for which the Consultant psychiatrist /GPwSI / specialist team is responsible

Assessment and liaison

- To make a diagnosis, and assess the suitability of the patient for acamprosate treatment
- To discuss with the patient, and their family or carers the proposed treatment, including the possible side effects, and to obtain their agreement and commitment to proceed. To arrange for complementary psychological treatment.
- To provide the patient and family or carers with written information about the drug. Suitable information may be found at <http://www.choiceandmedication.org/penninecare/medications/135>

Treatment initiation

- To arrange for liver function and urea and electrolyte tests to assess for hepatic or renal impairment.
- To prescribe and oversee the initial treatment, and assess its appropriateness for the patient or provide instructions to the GP for initiation where this has been agreed with the GP.

Liaison with General Practitioner (GP)

- To ask the GP whether they are willing to participate in shared care
- To provide details of dosage, and nature and frequency of monitoring
- To ensure that there are clear arrangements in place for specialist back-up and advice.
- To advise the GP when to refer back, and when and how to stop treatment (if appropriate).

Adverse reaction reporting

- To report any unexpected adverse drug reactions to the medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme <https://yellowcard.mhra.gov.uk>

Aspects of care for which the GP is responsible

Liaison with Secondary care/GPwSI

- To reply to the request for shared care as soon as possible
- To refer to the consultant/GPwSI /specialist team in the event of
 - a problem with the patient's treatment concordance
 - intolerable side effects
 - an unexpected adverse reaction to acamprosate
 - a suspected relapse

Patient care

- To prescribe the acamprosate at appropriate intervals
- To continue monitoring as agreed with specialist service
- To provide the patient with information and advice

Adverse reaction reporting

- To report any unexpected adverse drug reactions to the medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme <https://yellowcard.mhra.gov.uk>

6. Contra-indications, cautions, side-effects etc.

Contraindications [1]

- severe hepatic disease
- renal insufficiency if serum creatinine is greater than 120micromol/litre
- regular or excessive consumption of alcohol
- pregnancy
- breast feeding
- hypersensitivity to acamprosate tablets or any of its excipients

Cautions

- continued alcohol consumption (risks treatment failure) [4]
- patients over the age of 65 years and under the age of 18 years (safety has not been established in these patient groups) [1]

Side effects [1]

Commonly

- diarrhoea
- abdominal pain
- nausea

- vomiting
- flatulence
- reduced libido
- pruritis
- maculo-papular rash

Rarely

- hypersensitivity reactions, including urticaria, angio-oedema, anaphylactic reactions
- increased libido

7. Drug Interactions

None recorded

8. Back-up care available to GP from Drug and Alcohol services

Drugs and Alcohol services (Monday to Friday 9.00am – 4.45pm)

Rochdale Drug and Alcohol Service

11 – 13 St Chad's Court

Rochdale

OL16 1QU

Tel: 01706 **676500**

Oldham Drug and Alcohol Service

First Step and The Gateway

5 Horsedje Street

Oldham

OL1 3SX

Tel: 0161 716 3666

Stockport Drug and Alcohol Service

Cirtek House

Higher Hillgate

Stockport

SK1 3QD

Tel: 0161 716 4000

Tameside and Glossop Drug and Alcohol Service

Lees Street

Ashton under Lyne

OL6 8NU

Tel: 0161 716 3200

9. Statement of agreement

This guideline is a request by the consultant/specialist services to share the suggested care pathway for the patient.

if the GP is unable to agree to the sharing of care and prescribing this should be made known to the consultant/specialist service within 14 days, stating the specific nature of the concern.

10. Written information provided to the patient

Manufacturer's leaflet

<http://www.medicines.org.uk/emc/medicine/26337/PIL/Campral+EC>

Pennine Care Choice & Medication

<http://www.choiceandmedication.org/penninecare/medications/135>

11. Supporting References

1. Summary of Product Characteristics Campral

<http://www.medicines.org.uk/emc/medicine/1042/SPC/Campral+EC>

2. NICE Clinical Guideline CG 115 Alcohol-use disorders February 2011

www.nice.org.uk

3. Taylor, et al, *The Maudsley Prescribing Guidelines in Psychiatry*, 11th edition, Wiley-Blackwell (2012)

4. British National Formulary (BNF) 65 Mar-Sep 2013