ACAMPROSATE

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Further copies can be obtained from:

Pharmacy Department, Great Western Hospital
NHS Swindon
NHS Wiltshire

Addressograph label

Patient's Name _____

Specialist Prescriber Name _____

Specialist Prescriber Signature _____

Date _____

I agree to your request to prescribe Acamprosate in accordance with the attached shared care guideline:

GP Name _____

GP Signature _____

Date _____

ACAMPROSATE *(Campral EC®)*

For the treatment of alcohol dependence

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines how responsibility for prescribing **Acamprosate** might be shared between the specialist and the general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes this medication legally assumes clinical responsibility for **Acamprosate** and the consequences of its use.

RESPONSIBILITIES and ROLES

	Specialist prescriber responsibilities
1	Initiate treatment and prescribe until the patient is stabilised on Acamprosate and ready to move to 3-monthly monitoring.
2	Discuss the benefits (maintenance of abstinence from alcohol) and side effects of treatment with the patient e.g. diarrhoea, abdominal pain, impotence, decreased libido, ensuring that patients are advised what to do if side effects occur.
3	Ensure compatibility with other concomitant medication
4	Ask the GP whether he or she is willing to participate in shared care, and discuss the shared care arrangement with the patient & obtain their consent.
5	Supply GP with summary within 14 days of a specialist prescriber review
6	Review the patient's condition and monitor response to treatment at least annually or where deemed clinically necessary.
7	Give advice to the GP on when to stop treatment.
8	Report adverse events to the MHRA (Yellow Card Scheme) & GP.
9	Ensure that clear backup arrangements exist for GPs to obtain advice and support should they need it.

	General Practitioner responsibilities
1	Reply to the request for shared care as soon as practicable.
2	Prescribe medicine at the dose recommended once the patient has been stabilised on Acamprosate by the prescriber initiating treatment
3	Ensure compatibility of Acamprosate with other concomitant medication.
4	Monitor for effectiveness and refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs. Monitor at a recommended frequency of 3 monthly or more if judgement suggests.
5	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
6	Stop treatment on the advice of the specialist.
7	Report adverse events to the specialist and MHRA (Yellow Card Scheme).

	Patient's role
1	Attend all appointments with GP and specialist including appointments for blood tests and other monitoring.
2	Discuss with the specialist or GP if he or she does not have a clear understanding of the treatment.
3	Share any concerns in relation to their treatment with Acamprosate.
4	Inform specialist or GP of any other medication being taken, including over-the-counter products.
5	Report any adverse effects experienced to the specialist or GP whilst taking the medicine, who will advise on the most appropriate course of action to be taken.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist in Wiltshire Substance Misuse Service: Dr Fergus Law	07989 240981	N/A	N/A	Fergus.Law@Turning-Point.co.uk
Other: Wiltshire Substance Misuse Service bases in Chippenham, Trowbridge and Salisbury,	0345 6036993		Chippenham: 01249 440279; Trowbridge: 01225 718989; Salisbury: 01722 343009	N/A

SUPPORTING INFORMATION

Summary of condition
Alcohol dependence

Licensed indications
To maintain abstinence in alcohol-dependent patients.

Expected / established place in local treatment pathway
Acamprosate is routinely offered as an option for treatment following alcohol detoxification

Dosage and administration

Adults 18 – 65 years:
In patients weighing 60kg or more, SIX tablets divided into three daily doses with meals (2 tablets in the morning, 2 tablets at noon and 2 tablets at night).

In patients weighing less than 60kg, FOUR tablets divided into three daily doses with meals (2 tablets in the morning, 1 at noon and 1 at night).

Acamprosate should usually be prescribed for up to 6 months, or longer for those benefiting from the drug who want to continue with it (SPC recommends one year).

Contra-indications and precautions for use
Contraindications:
- Acamprosate should not be administered to children and the elderly.
- Patients with a known hypersensitivity to acamprosate or to any of the excipients
- Pregnant and Breastfeeding women
- Patient's with renal insufficiency (serum creatinine >120 micromol/L)

Caution:
- Patient's with severe hepatic insufficiency (Childs-Pugh Classification C).

Side-effects
For a full list, please refer to SPC: www.medicines.org.uk and also the current BNF www.bnf.org/bnf

The following definitions relate to the frequency: very common (1/10), common (1/100, < 1/10), uncommon (1/1,000, < 1/100), rare (1/10,000, < 1/1,000), very rare (< 1/10,000):

Very common: diarrhoea
Common side effects: include abdominal pain, nausea, vomiting, flatulence loss of appetite, trouble sleeping, rash, pruritis, impotence, loss of libido, frigidity and weakness.
Uncommon: Increased libido.
Very rare: Hypersensitivity reactions including urticaria, angio-oedema or anaphylactic reactions.
Not known: Vesiculo-bullous eruptions.

If a patient is unduly troubled by these symptoms it would be reasonable to discontinue Acamprosate. Serious side-effects are very rare and include allergic reactions upon initiation and cardiovascular effects. Cardiovascular effects include palpitations, vasodilation, hypertension and syncope. Urgent medical attention should be sought if these develop.

This medicine has / does not have black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA.

Abuse potential:
Non-clinical studies suggest that acamprosate has little or no abuse potential. No evidence of dependence on acamprosate was found in any clinical study thus demonstrating that acamprosate has no significant dependence potential

Monitoring

Parameter	Frequency of monitoring	Action (adjustment and referral back to the Wiltshire Substance Misuse Service)
Abstinence from alcohol	Shortly after initiation of treatment, then one week later, then one month later, then 3 monthly or as clinically indicated.	Relapse to alcohol dependence – refer back to Wiltshire Substance Misuse Service if client motivated to seek treatment
Overall health and compliance	Three monthly	No LFTs are required for acamprosate but the patient and GP may find it useful to monitor as a means of indicating health improvement due to abstinence. 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 Non compliance – review by GP and refer back to Wiltshire Substance Misuse Service if client motivated to seek treatment

Drug Interactions

Acamprosate is excreted by the kidneys and therefore is not affected by drugs that alter liver metabolism. There are no dangerous drug interactions reported.

The concomitant intake of alcohol and acamprosate does not affect the pharmacokinetics of either alcohol or acamprosate. The administration of food diminishes the bioavailability of the drug compared with its administration in the fasting state.

Pharmacokinetic studies indicate that administration of disulfiram or diazepam does not affect the pharmacokinetics of acamprosate. Co-administration of naltrexone with acamprosate produces an increase in acamprosate levels, however, no adjustment of dosage is necessary. The pharmacokinetics of naltrexone and its major metabolite 6-beta-naltrexol were unaffected following co-administration with acamprosate.

Other concomitant therapies: In clinical trials, the safety profile in subjects treated with acamprosate concomitantly with anxiolytics, hypnotics and sedatives (including benzodiazepines), or non-opioid analgesics was similar to that of subjects taking placebo with these concomitant medications. Patients taking acamprosate concomitantly with antidepressants more commonly reported both weight gain and weight loss, compared with patients taking either medication alone.

Cost
£28.80 per pack of 168 tablets (Drug Tariff, February 2014).

References

- NICE clinical guideline 115: February 2011 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence.
- Summary of Product Characteristics www.medicines.org.uk
- Acamprosate SCA BNSSG (Sept 2013). http://www.awp.nhs.uk/advice-support/medicines/shared-care/

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Date of review
2 years from publication or earlier if change in guidance.