561FM.1 NALTREXONE FOR USE IN TREATMENT OF ALCOHOL DEPENDENCY IN ADULTS 18 YEARS AND OVER
Amber Initiation Guidelines

This guideline provides prescribing and monitoring guidance for naltrexone 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

Naltrexone is an opioid-receptor antagonist, which is useful as an adjunct in the treatment of alcohol dependence after a successful withdrawal completed under specialist supervision.
Naltrexone is a drug used to support the treatment of chronic alcoholism by blocking the body's receptors that produce euphoric feelings when you drink.
Naltrexone is a non-addictive and non-narcotic drug, which means that users will not develop dependence or other addictive traits when taking the medication.

SUPPORTING INFORMATION

Naltrexone is an established drug with a known side effect profile. It is used as second line therapy for treatment of alcohol abstinence if acamprosate is inappropriate due to contraindications, inefficiency or intolerance.

CONTRAINDICATIONS

- Patients currently dependent on opioids.

PRECAUTIONS

- Pregnancy. - Use only if benefit outweighs risk
- Breast-feeding. - Avoid – potential toxicity
- Hepatic impairment - Manufacturer advises caution in mild to moderate impairment. Avoid in severe or acute impairment, acute hepatitis or hepatic failure
- Renal impairment - Avoid in severe impairment

DOSAGE

- Adult dose half a tablet (25 mg) once daily on the first day then increased if tolerated to one tablet (50 mg) daily.

TIME TO RESPONSE

- Immediate

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 general practitioner (GP) surgery (ORB do not have access to OrderComms (ICE)).
- Pre-treatment screening for opioid dependency/use to be done via urine drug screen, withdrawal assessment and medical summary information.
- Prior to request for naltrexone prescribing to be continued with the patient's 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.

RESPONSIBILITIES

ORB

- A comprehensive assessment by the recovery worker and specialist prescriber 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, U&Es. The results to 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.
- 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 naltrexone.
- 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 naltrexone.
- 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 6 months (12 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 of 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 12 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 6 months (12 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 12 months they can contact ORB for advice on further prescribing.
- 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 naltrexone 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 from GP.

GP

- Email ORB via secure nhs.net email to acknowledge the continued prescribing of naltrexone 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 12 months if it benefits the patient and patient wants to continue taking medication. The GP will receive 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.
- Ensure the patient's personal monitoring card is kept up to date and is brought to all appointments.
- 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 naltrexone therapy in adults.

Monitoring by ORB

- Service users taking naltrexone should stay under supervision, at least monthly, for 6 months, and at reduced but regular intervals if the drug is continued after 6 months.
- Do not request blood tests routinely, 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 naltrexone. 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 naltrexone 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

Side Effects	Action
Common	
• Anxiety	Often transient. If possible continue after reassuring patient.
• Abnormal appetite	Often transient. If possible continue after reassuring patient.
• Arthralgia	Often transient. If possible continue after reassuring patient.
• Asthenia	Often transient. If possible continue after reassuring patient.
• Chest pain	Discontinue if symptoms severe
• Chills	Often transient. If possible continue after reassuring patient.
• Constipation	Often transient. If possible continue after reassuring patient.
• Diarrhoea	Often transient. If possible continue after reassuring patient.
• Dizziness	Often transient. If possible continue after reassuring patient. Advise patient not to engage in hazardous activities requiring mental alertness e.g. operating machinery.
• Eye disorders	Discontinue treatment
• Headache	Often transient. If possible continue after reassuring patient.
• Hyperhidrosis	Often transient. If possible continue after reassuring patient.
• Mood altered	If mood changes are significant then discontinue treatment.
• Myalgia	Often transient. If possible continue after reassuring patient.
• Nausea	Often transient. If possible continue after reassuring patient.
• Palpitations	Often transient. If possible continue after reassuring patient. If significant then discontinue treatment.
• Sexual dysfunction	Often transient. If possible continue after reassuring patient. If significant then discontinue treatment.
• Skin reactions	*Often transient. If possible continue after reassuring patient. If significant then discontinue treatment.*
• Sleep disorders	Often transient. If possible continue after reassuring patient. If significant then discontinue treatment.
• Tachycardia	Often transient. If possible continue after reassuring patient. If significant then discontinue treatment.
• Thirst	Often transient. If possible continue after reassuring patient.
• Vomiting	Often transient. If possible continue after reassuring patient. If significant then discontinue treatment.
Rare • Depression	Stop and inform ORB
• Hepatic dysfunction	Stop and inform ORB
• Speech disorders	Stop and inform ORB
• Suicidal ideation	Stop and inform ORB
• Tinnitus	Stop and inform ORB
Very Rare • Immune thrombocytopenic purpura	Stop and inform ORB
• Exanthema	Stop and inform ORB
• Hallucinations and tremor	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/chapter/1-Guidance
3) BNF naltrexone: https://bnf.nice.org.uk/drug/naltrexone-hydrochloride.html
4) NICE guidance drug misuse and psychosocial interventions https://www.nice.org.uk/guidance/cg51

See also:

Guideline 560FM Acamprosate 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.