

Nalmefene (Selincro®)

<p>Background Information</p>	<p>Nalmefene is a partial opiate antagonist that affects the “reward pathways” in the brain reducing the pleasure felt when alcohol is consumed</p> <p><u>Target population:</u> Adult (limited data in elderly, no data for <18yrs), without significant levels of alcohol dependence, who have adequate social support. Threshold alcohol consumption: >7.5 units (60g) daily in men, >5 units (40g) daily in women.</p> <p>Licensed indication: alcohol reduction, in conjunction with ongoing psychosocial intervention.</p> <p><u>Initial assessment:</u> Clinical assessment of drinking, presence of dependence, physical or psychiatric comorbidities. Complete screening questionnaire (e.g. LDQ – See Appendix A). Goals of treatment, level of support.</p> <p><u>Brief intervention:</u> Obtain baseline liver function and U&E if no contraindications to nalmefene and patient meets suitability criteria. Schedule follow up appointment after two weeks, with drinks diary.</p> <p><u>Follow up:</u> Review drinking over preceding weeks. If continued drinking at higher than recommended levels, nalmefene may be commenced at this time in conjunction with structured psychosocial intervention.</p> <p><u>Suitability:</u> People who are drinking more than recommended limits, people who do not meet criteria for alcohol detoxification (no physical withdrawals). People who can engage with the psychosocial component of treatment. People who continue to drink at higher levels two weeks after initial appointment with brief intervention.</p> <p>See Appendix B for a summary of the use of nalmefene.</p>
<p>BNF therapeutic class</p>	<p>4.10. Drugs used in substance dependence</p>
<p>Indication</p>	<p>Reduction of alcohol consumption in adults with alcohol dependence without physical withdrawals and not requiring immediate detoxification.</p>
<p>Dosage and administration</p>	<p>Single dose of 18mg daily, as required. 1 dose to be taken on days when there is a perceived risk of drinking alcohol. Dose to be taken 1-2 hours prior to when drinking likely to occur, or as soon as possible after drinking has commenced. No adjustments for elderly, mild/moderate renal or hepatic impairment. No data in under 18yrs</p>
<p>Cautions and Contraindications</p>	<p>Contraindications Hypersensitivity. Opioid use (those currently prescribed opioids, opioid addiction, withdrawal, recent use of opioids) Severe hepatic impairment Severe renal impairment (eGFR,30ml/min per 1.73m²). Recent history of acute alcohol withdrawal</p> <p>Cautions: Need for increased doses of opiates in emergencies, risk of respiratory depression. Discontinue 1 week before planned opiate use e.g. elective surgery. Not been evaluated in unstable psychiatric disease.</p>

	Trials excluded those with ALT or AST >3x upper limit of normal Not recommended in pregnancy No breastfeeding data.
Adverse Drug Reactions	<p>Very common (>10%): nausea, dizziness, insomnia, headache – mild/moderate, initiation, short duration.</p> <p>Common (1-9%): decreased appetite, sleep problems, confusional state, restlessness, decreased libido, tremor, disturbance in attention, paraesthesia, hypoaesthesia, tachycardia, palpitations, vomiting, dry mouth, hyperhidrosis, muscle spasms, fatigue, asthenia, malaise, feeling abnormal, weight decreased.</p> <p>Frequency not known: hallucinations, dissociation.</p> <p>Confusional state, hallucinations, dissociation – majority mild/moderate, initiation, resolved with continued treatment and did not recur. Could have been related to alcohol withdrawal or psychiatric illness.</p> <p>Overdose data – data up to 108mg/day regularly, and single dose of 450mg – no apparent major concerns of toxicity.</p>
Monitoring	Ongoing monitoring of LFT and U&E not required. Where baseline values are abnormal, 3-monthly measurement while prescription continues is suggested.
Interactions	<p>UGT2B7 inhibitors can increase nalmefene exposure.</p> <ul style="list-style-type: none"> E.g. diclofenac, fluconazole, medroxyprogesterone acetate, meclofenamic acid <p>UGT inducers can lead to subtherapeutic nalmefene concentrations</p> <ul style="list-style-type: none"> E.g. dexamethasone, Phenobarbital, rifampicin, omeprazole. <p><u>Opioid agonists may be blocked by nalmefene</u></p>

Contact names and details

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References

- British National Formulary. March 2015. Available at: <https://www.medicinescomplete.com/mc/bnf/current/> Accessed: 11/05/15
- Nalmefene (Selincro®). Summary of Product Characteristics. January 2015. Available at: <https://www.medicines.org.uk/emc/medicine/27609> Accessed: 11/05/15
- Nalmefene for reducing alcohol consumption in people with alcohol dependence. NICE Technology Appraisal TA325. November 2014. Available at: <http://www.nice.org.uk/guidance/ta325> Accessed: 11/05/15

Development Process

This guideline was developed following an AMBER-G (Amber with guidance) classification status of Nalmefene by the Barnsley Area Prescribing Committee in February 2015. This information has been subject to consultation and endorsement by the LMC on 9th June 2015.

Appendix A

Leeds Dependence Questionnaire - LDQ

Here are some questions about the importance of alcohol or other drugs in your life. Think about the main substance you have been using over the **last 4 weeks** and tick the closest answer to how you see yourself

	Never 0	Sometimes 1	Often 2	Nearly Always 3
Do you find yourself thinking about when you will next be able to have another drink or take more drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is drinking or taking drugs more important than anything else you might do during the day?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that your need for drink or drugs is too strong to control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you plan your days around getting and taking drink or drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you drink or take drugs in a particular way in order to increase the effect it gives you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you drink or take drugs morning, afternoon and evening?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel you have to carry on drinking or taking drugs once you have started?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is getting an effect more important than the particular drink or drug you use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you want to take more drink or drugs when the effects start to wear off?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you find it difficult to cope with life without drink or drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Leeds Dependence Questionnaire (LDQ)

The LDQ (www.leedspft.nhs.uk/our_services/leeds_addiction_unit/RESULT) is derived from a psychological understanding of the nature of dependence and is, therefore, suitable for measuring dependence during periods of substance use or abstinence. The LDQ is an indicator of how addicted a person is and, therefore, how difficult it will be to achieve a positive outcome.

For help seeking populations the LDQ is a reasonable proxy for substance use, however, for people who are socially quite stable, employed and having functional families, heavy drinking or other drug use is less well correlated with dependence.

There are 10 items scored 0-3.

Cut offs are:

<10 = low dependence;

10-22 = medium dependence; and

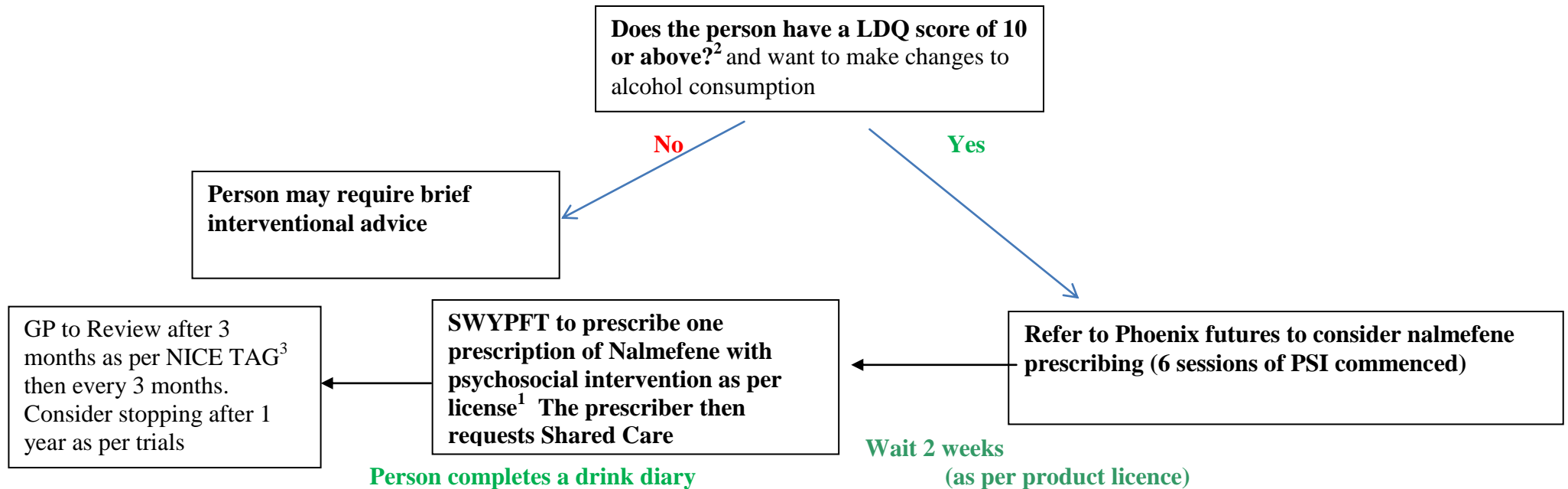
>22 = high dependence.

Amber with Guidance= To be initiated and titrated to a stable dose in secondary care with follow up prescribing and monitoring by primary care where deemed appropriate.

Appendix B

Flowchart for the use of Nalmefene (Selincro™ ▼)

Selincro® is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level without physical withdrawal symptoms and who do not require immediate detoxification.¹



References

1. SPC Selincro. January 2015. Available at: <http://www.medicines.org.uk/emc/medicine/27609>
2. See appendix A – Leeds Dependence Questionnaire
3. NICE TAG 325 <http://www.nice.org.uk/guidance/TA325>