

## Nalmefene (Selincro®)

<p><b>Background Information</b></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 &lt;18yrs), without significant levels of alcohol dependence, who have adequate social support.                  Threshold alcohol consumption: &gt;7.5 units (60g) daily in men, &gt;5 units (40g) daily in women.                  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. SADQ – See Appendix A). Goals of treatment, level of support.</p> <p><u>Brief intervention:</u>                  Obtain baseline liver function and U&amp;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><b>BNF therapeutic class</b></p>	<p>4.10. Drugs used in substance dependence</p>
<p><b>Indication</b></p>	<p>Reduction of alcohol consumption in adults with alcohol dependence <b>without physical withdrawals and not requiring immediate detoxification.</b></p>
<p><b>Dosage and administration</b></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.</p> <p>No data in under 18yrs</p>
<p><b>Contraindications and Cautions</b></p>	<p><b>Contraindications</b>                  Hypersensitivity.                  Opioid use (those currently prescribed opioids, opioid addiction, withdrawal, recent use of opioids)                  Severe hepatic impairment                  Severe renal impairment (eGFR,30ml/min per 1.73m<sup>2</sup>).                  Recent history of acute alcohol withdrawal</p>

**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.

	<p><b>Cautions:</b>            Need for increased doses of opiates in emergencies, risk of respiratory depression. Discontinue 1 week before planned opiate use e.g. elective surgery            Patients requiring intermittent opiate analgesia for a recurring problem will need to temporarily discontinue Nalmefene in order for the opiate to be effective.            Not been evaluated in unstable psychiatric disease.            Trials excluded those with ALT or AST &gt;3x upper limit of normal            Not recommended in pregnancy            No breastfeeding data.</p>
<b>Adverse Drug Reactions</b>	<p>Very common (&gt;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>
<b>Monitoring</b>	<p>Ongoing monitoring of LFT and U&amp;E not required. Where baseline values are abnormal, 3-monthly measurement while prescription continues is suggested.</p>
<b>Interactions</b>	<p>UGT2B7 inhibitors can increase Nalmefene exposure.</p> <ul style="list-style-type: none"> <li>E.g. <b>diclofenac</b>, fluconazole, medroxyprogesterone acetate, meclofenamic acid</li> </ul> <p>UGT inducers can lead to subtherapeutic Nalmefene concentrations</p> <ul style="list-style-type: none"> <li>E.g. dexamethasone, Phenobarbital, rifampicin, <b>omeprazole</b>.</li> </ul> <p><b><u>Opioid agonists may be blocked by Nalmefene</u></b></p>

### **Contact names and details**

<b>Contact Details</b>	<b>Telephone number</b>	<b>Email</b>
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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
- Choice and Medication Patient Information Leaflet. <https://www.choiceandmedication.org/humankind/medication/Nalmefene/>
- <sup>1</sup> Stockwell, T., Sitharan, T., McGrath, D. & Lang. (1994). The measurement of alcohol dependence and impaired control in community samples. *Addiction*, 89, 167-174.

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### **Development Process**

*This guideline was developed following an AMBER-G (Amber with guidance) classification status of Nalmefene by the Barnsley Area Prescribing Committee (APC) in February 2015. This information has been updated and has been endorsed by the APC on 11<sup>th</sup> August 2021.*

## Appendix A

### SEVERITY OF ALCOHOL DEPENDENCE QUESTIONNAIRE (SADQ-C)<sup>1</sup>

NAME: \_\_\_\_\_ AGE: \_\_\_\_\_ DATE: \_\_\_\_\_

Please recall a typical period of heavy drinking in the last 6 months.

When was this?      Month..... Year.....

Please answer all the following questions about your drinking by circling your most appropriate response. Your score will be calculated by the doctor or nurse.

#### **During that period of heavy drinking;**

1. The day after drinking alcohol, I woke up feeling sweaty.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
2. The day after drinking alcohol, my hands shook first thing in the morning.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
3. The day after drinking alcohol, my whole body shook violently, first thing in the morning if I did not have a drink.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
4. The day after drinking alcohol, I woke up absolutely drenched in sweat.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
5. The day after drinking alcohol, I dread waking up in the morning.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
6. The day after drinking alcohol, I was frightened of meeting people first thing in the morning  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
7. The day after drinking alcohol, I felt at the edge of despair when I awoke.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
8. The day after drinking alcohol, I felt very frightened when I awoke.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
9. The day after drinking alcohol, I liked to have an alcoholic drink in the morning.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
10. The day after drinking alcohol, I always gulped my first few alcoholic drinks down as quickly as possible.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
11. The day after drinking alcohol, I drank more alcohol to get rid of the shakes.  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
12. The day after drinking alcohol, I had a very strong craving for a drink when I awoke  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
13. I drank more than a quarter of a bottle of spirits in a day (OR 1 bottle of wine OR 7 beers).  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
14. I drank more than half a bottle of spirits per day (OR 2 bottles of wine OR 15 beers).  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
15. I drank more than one bottle of spirits per day (OR 4 bottles of wine OR 30 beers).  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score
16. I drank more than two bottles of spirits per day (OR 8 bottles of wine OR 60 beers).  
ALMOST NEVER (0)    SOMETIMES (1)    OFTEN (2)    NEARLY ALWAYS (3)      score

### Imagine the following situation:

- a) You have been **completely off drink for a few weeks**
- b) You then drink **very heavily for two days**

How would you feel the **morning after** those two days of drinking?

17. I would start to sweat. ALMOST NEVER (0) SOMETIMES (1) OFTEN (2) NEARLY ALWAYS (3)	score <input type="text"/>
18. My hands would shake. ALMOST NEVER (0) SOMETIMES (1) OFTEN (2) NEARLY ALWAYS (3)	score <input type="text"/>
19. My body would shake. ALMOST NEVER (0) SOMETIMES (1) OFTEN (2) NEARLY ALWAYS (3)	score <input type="text"/>
20. I would be craving for a drink. ALMOST NEVER (0) SOMETIMES (1) OFTEN (2) NEARLY ALWAYS (3)	score <input type="text"/>
<hr/>	
TOTAL SCORE:	<input type="text"/>

### NOTES ON THE USE OF THE SADQ

The Severity of Alcohol Dependence Questionnaire was developed by the Addiction Research Unit at the Maudsley Hospital. It is a measure of the severity of dependence. The AUDIT questionnaire, by contrast, is used to assess whether there is a problem with dependence.

The SADQ questions cover the following aspects of dependency syndrome:

- physical withdrawal symptoms
- affective withdrawal symptoms
- relief drinking
- frequency of alcohol consumption
- speed of onset of withdrawal symptoms.

### Scoring

Answers to each question are rated on a four-point scale:

Almost never: 0

Sometimes: 1

Often: 2

Nearly always: 3

**A score of 31 or higher** indicates "severe alcohol dependence".

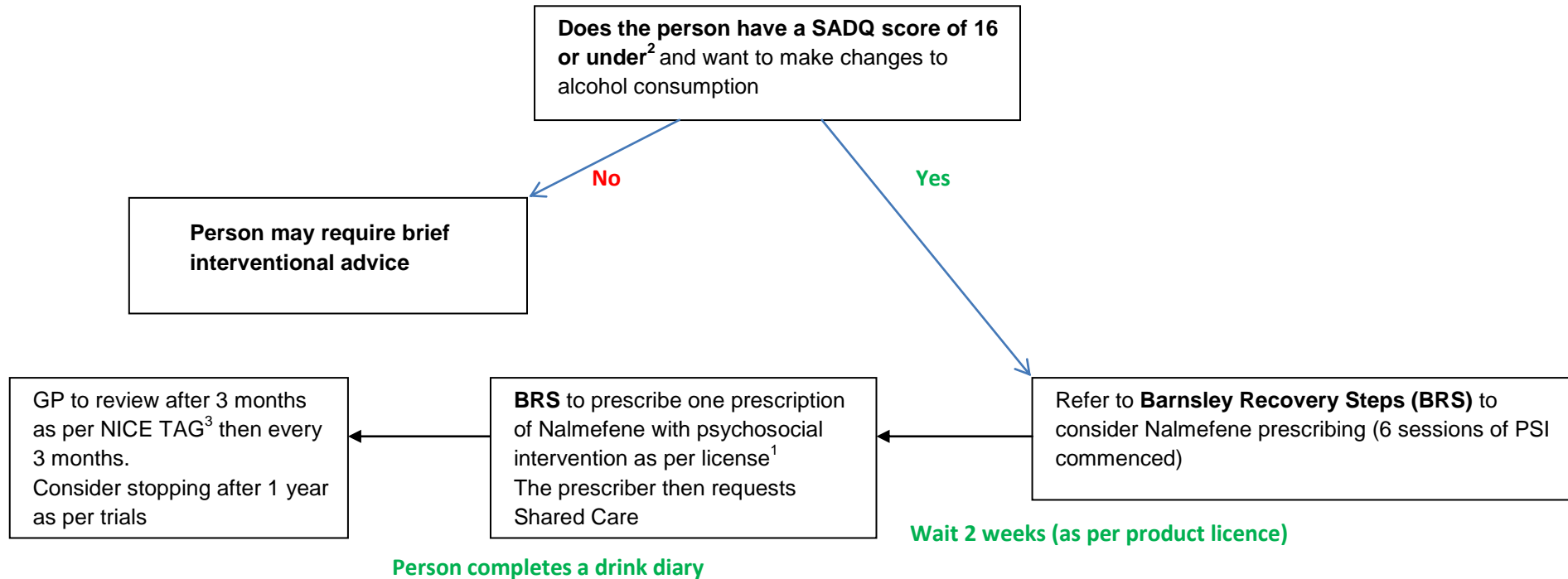
**A score of 16 -30** indicates "moderate dependence"

**A score of below 16** usually indicates only a mild physical dependency.

## 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.<sup>1</sup>



#### References

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