

Berkshire West CCGs Alcohol Treatment Pathway for Nalmefene (Selincro) Primary Care Guidance

Nalmefene (trade name Selincro) was given approval by NICE in November 2014 and should be available to use with patients from the 24th February 2015.

Nalmefene is recommended as an option for reducing alcohol consumption, for people with alcohol dependence, who have a high drinking risk level (defined as alcohol consumption of more than 60 g per day or 7.5 units for men and more than 40 g per day or 5 units for women per day) without physical withdrawal symptoms and who do not require immediate detoxification.

Nalmefene should:

- only be prescribed in conjunction with continuous psycho-social support focused on treatment adherence and reducing alcohol consumption
- only be initiated in patients who continue to have a high drinking risk level 2 weeks after initial assessment.

Nalmefene (Selincro) is an opioid receptor modulator, which exhibits antagonist activity at the mu and delta opioid receptors, and partial agonist activity at the kappa opioid receptors.

Nalmefene is available as an 18 mg film-coated tablet and is priced at £42.42 for a pack of 14 tablets or £84.84 for a packet of 28 tablets (£3.03 per tablet). It is taken orally at a maximum dose of 1 tablet daily on an 'as-needed' basis.

Adverse reactions for Nalmefene include: nausea, dizziness, insomnia and headaches

NICE's full technology appraisal 'Nalmefene for reducing alcohol consumption in people with alcohol dependence' (NICE technology appraisal guidance 325) was issued November 2014. The guidance is available here:

<https://www.nice.org.uk/guidance/ta325>

For more information on the drug see appendix A

Nalmefene Pathway for Berkshire West CCGs

(see Appendix B for shortened GP version)

Identification and Brief Advice

When a patient presents with an indication of harmful alcohol use a recognised short screening tool should be used to initially assess the level of risk (suggested tool is AUDIT-C, see appendix C)

If the patient is scored as a low risk drinker ('negative'), they should be congratulated and the benefits of low risk drinking should be reinforced. The patient should be referred to

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|-----------|--------------------------|-------------|----------|
| Author | A Scott | Date | May 2015 |
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| Version | 1.0 | 1 of 9 | |

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NHS choices website <http://www.nhs.uk/Livewell/alcohol/Pages/Alcoholhome.aspx> which has some useful applications for tracking drinking as well as explaining the risks involved and tips to help cut back on drinking.

If the patient is scored as having an 'increased' or 'high' drinking risk ('positive') the practitioner can either refer to the following:

| | |
|--|--|
| <p>Swanswell (For Newbury & District CCG patients) Telephone: 0300 003 7025 Fax: 08718952310 Email: wberksref@swanswell.org Address: Station Road, Newbury, Berkshire RG14 7LP</p> | <p>IRiS Reading (For South Reading/North and West Reading CCG patients) Website: http://www.cranstoun.org/our-services/alcohol-drugs-community/iris-reading/Health, access & engagement services – Queens Road Tel: 0118 956 7441 Fax: 0118 956 6466 Address: 38 Queens Road, Reading, Berkshire, RG1 4AU Treatment & Recovery services – Waylen Street Tel: 0118 955 7333 Fax: 0118 955 7344 Address: 4 Waylen Street, Reading, Berkshire, RG1 7UR Recovery & wellbeing services – Oxford Road Tel: 0118 959 6118 Fax: 0118 959 8695 Address: 159 Oxford Road, Reading, Berks, RG1 7UY</p> |
| <p>SMART (For Wokingham CCG patients) Contact: 0118 977 2022 Email: wokingham@smartcjs.org.uk Website: http://www.smartcjs.org.uk/ Address: 38 Station Road, Wokingham, RG40 2AE Opening times: Monday and Tuesday - 9am-5pm Wednesday and Thursday: 9am-8pm Friday - 9am-4.30pm</p> | |

Once the full AUDIT is completed the score will help guide the appropriate support for the patient. As a guide the following scores should result in the following:

Score 0-7: Low Risk drinker - Congratulate patients as a 'low risk' drinker. Reinforce the benefits of continuing to drink at this level.

Score 8-15: Increasing Risk drinker -has an increased risk of developing an alcohol related illness. The patient should be given advice using the brief advice tool, highlighting the risks of continuing to drink at these levels and the benefits of cutting down.

Score 16-19: High risk drinker - (GP refer to AIT) the patient should receive advice as above, be asked to complete a drinks diary (or details of a free app at drinkaware.co.uk , available on iOS and Android that can track units and calories) and set a drinking reduction goal. A follow up appointment is made for 2 weeks later at AIT.

Score 20+: Possible dependence - (GP refer to AIT) discussion should be had on the amount the patient drinks, whether they suffer any withdrawal symptoms, have an alcohol treatment history, other comorbidities etc. If it is determined the patient has a 'mild dependency', (approximately a score below 25) and no complications, then the same action could be taken as a 'high risk' drinker. All others should be referred to a

| | | | |
|-----------|--------------------------|-------------|----------|
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| Job Title | Commissioning Pharmacist | Review Date | May 2018 |
| Version | 1.0 | 2 of 9 | |

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specialist alcohol treatment service for a full assessment and entry into specialist treatment.

2 week review

For high risk/mild dependent drinkers a 2 week follow up appointment is made following the initial engagement. If during this review the patient has reduced their alcohol consumption and is making sufficient improvement, then the AIT will continue with psycho-social support only. However if the patient has not made progress, but continues to be engaged and motivated to change, then Nalmefene could be considered.

The patient will be given information on Nalmefene: how it works, how it should be taken, expected commitment to continue with psycho-social support, side effects etc. If the patient is in agreement and is suitable for the drug, then the AIT will complete a letter for the patient to take back to their GP requesting the drug be prescribed (Appendix F).

The patient will make an appointment to see their GP and present the letter.

The Alcohol Interventions Team will make an appointment for a 2 week review.

GP Prescribing

When presented with the letter advising the GP of the patient's suitability to receive Nalmefene, **this is advice only**. This advice does not suggest the patient is medically suitable for the drug as the Alcohol Interventions Team will not have the full medical history of the patient. Please refer to Appendix A for drug information.

- To aid compliance, please ensure patient is aware that during initiation they may have transient side effects of nausea, dizziness, insomnia. In majority of cases this stops after 1 week.
- Advise to take 1st tablet when they do not have work the following day.
- Ensure the patient has the patient leaflet and "opioid receptor antagonist card" What patient leaflet and opioid receptor card. There will be a patient info leaflet in the box of tablets which the pharmacy will provide
- The patient is to take a maximum of one tablet/day as needed (PRN) only on days when drinking, ideally, 1-2hrs before anticipated drinking risk, but can be taken immediately.

GPs may wish to prescribe initially for 2 weeks only and then monthly assuming compliance with psycho-social support and advice from AIT.

Psycho-social Support

The AIT will see the patient for regular psycho-social support whilst the patient is receiving Nalmefene. The patient will be seen at 2,4,8,12 weeks. Each time the GP will be sent a brief progress report in a review template, (Appendix G). This will include advice to continue prescribing or to cease (due to very good progress, or failure to attend appointments).

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|-----------|--------------------------|-------------|----------|
| Author | A Scott | Date | May 2015 |
| Job Title | Commissioning Pharmacist | Review Date | May 2018 |
| Version | 1.0 | 3 of 9 | |

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At 12 and 24 weeks the AIT will recommend if another 12 week course is appropriate. The patient should be taking Nalmefene less frequently by this point. The AIT will continue with 4 week reviews.

If the patient no longer requires Nalmefene as their drinking goal is achieved, the GP will be advised by the AIT to consider ceasing prescribing. Alternatively if the patient fails to achieve drinking reduction, then AIT will consider a referral for alternative options, such a detoxification or alternative prescribing (Naltrexone, Acamprosate or Disulfiram).

| | | | |
|-----------|--------------------------|-------------|----------|
| Author | A Scott | Date | May 2015 |
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| Version | 1.0 | 4 of 9 | |

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Appendix A

Selincro®.(nalmefene) Tablets Prescribing information:

Indication: Reduction of alcohol consumption in adults with alcohol dependence who have a high drinking risk level (DRL) [i.e men >60g/day, women >40g/day], without physical withdrawal symptoms and who do not require immediate detoxification. Selincro should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Selincro should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.

Posology & administration: At initial visit, evaluate the patient's clinical status, alcohol dependence, and level of alcohol consumption (based on patient reporting). Thereafter, the patient should record his or her alcohol consumption for approximately two weeks. Selincro may be initiated at the next visit in patients who continue to have a high DRL over this period, in conjunction with psychosocial intervention focused on treatment adherence and reducing alcohol consumption. Evaluate the patient's response to treatment and continued need on a regular basis. Assess patient's progress in reducing alcohol consumption, overall functioning, treatment adherence and potential side effects.

Caution if Selincro is prescribed for more than 1 year. Selincro is taken as-needed: on each day the patient perceives a risk of drinking alcohol, one tablet should be taken, preferably 1-2 hours prior to the anticipated time of drinking. If the patient has started drinking alcohol without taking Selincro, the patient should take one tablet as soon as possible.

Children and adolescents (<18 years): Safety and efficacy have not been established.

Elderly (>65 years): No dosage adjustment required. Limited clinical data so caution advised.

Renal impairment: No dosage adjustment required in mild or moderate impairment, but exercise caution e.g. more frequent monitoring. Do not use in severe renal impairment (eGFR <30ml/min per 1.73m²).

Hepatic impairment: No dosage adjustment in mild or moderate impairment, but exercise caution e.g. more frequent monitoring. Do not use in severe impairment. Caution in patients with elevated ALAT or ASAT (>3 times ULN).

Contraindications: Hypersensitivity to active substance or excipients. Patients taking opioids, who have current or recent opioid addiction, those with acute symptoms of

| | | | |
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| Job Title | Commissioning Pharmacist | Review Date | May 2018 |
| Version | 1.0 | 5 of 9 | |

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opioid withdrawal, or if recent use of opioids is suspected. Recent history of acute alcohol withdrawal syndrome.

Fertility, pregnancy and lactation: Not recommended during pregnancy. It is unknown whether nalmefene is excreted in human milk. A risk to newborn/infants cannot be excluded.

Special warnings & precautions: Not for patients for whom immediate treatment goal is abstinence. Negligible influence on ability to drive and use machines. If opioids must be administered to a patient taking Selincro, the amount of opioid required to obtain the desired effect may be greater than usual. Closely monitor patient for symptoms of respiratory depression as a result of the opioid administration and for other adverse reactions. Titrate the dose of opioid individually. If unusually large doses are required, observe closely. Temporarily discontinue Selincro for 1 week prior to anticipated use of opioids, e.g. during elective surgery. Advise patients to inform their healthcare professional of last Selincro intake if opioid use is necessary.

Caution in: patients with current psychiatric comorbidity such as major depressive disorder; patients with history of seizure disorder, including alcohol withdrawal seizures.

Do not use in: patients with galactose intolerance, Lapp lactase deficiency, or glucose galactose malabsorption.

Drug interactions: Co-administration with potent inhibitors of UGT2B7 (e.g. diclofenac, fluconazole, medroxyprogesterone acetate, meclufenamic acid) may increase exposure to nalmefene. Concomitant use with UGT inducers (e.g. dexamethasone, phenobarbital, rifampicin, omeprazole) may lead to subtherapeutic nalmefene plasma levels. If taken with opioid agonists the patient may not benefit from the opioid agonist.

Adverse events: The most common adverse reactions reported in clinical trials were nausea, dizziness, insomnia and headache (very common =1/10). The majority of reactions were mild or moderate, associated with treatment initiation and of short duration. The following were reported as common (=1/100 to <1/10): decrease in appetite, sleep disorder, confusional state, restlessness, decrease in libido (including loss of libido), somnolence, tremor, disturbance in attention, paraesthesia, hypoaesthesia, tachycardia, palpitations, vomiting, dry mouth, hyperhidrosis, muscle spasms, fatigue, asthenia, malaise, feeling abnormal, and decrease in weight. In addition hallucinations (including auditory, tactile, visual or somatic hallucinations) (frequency unknown) have also been reported. Prescribers should consult the full Summary of Product Characteristics in relation to other side effects.

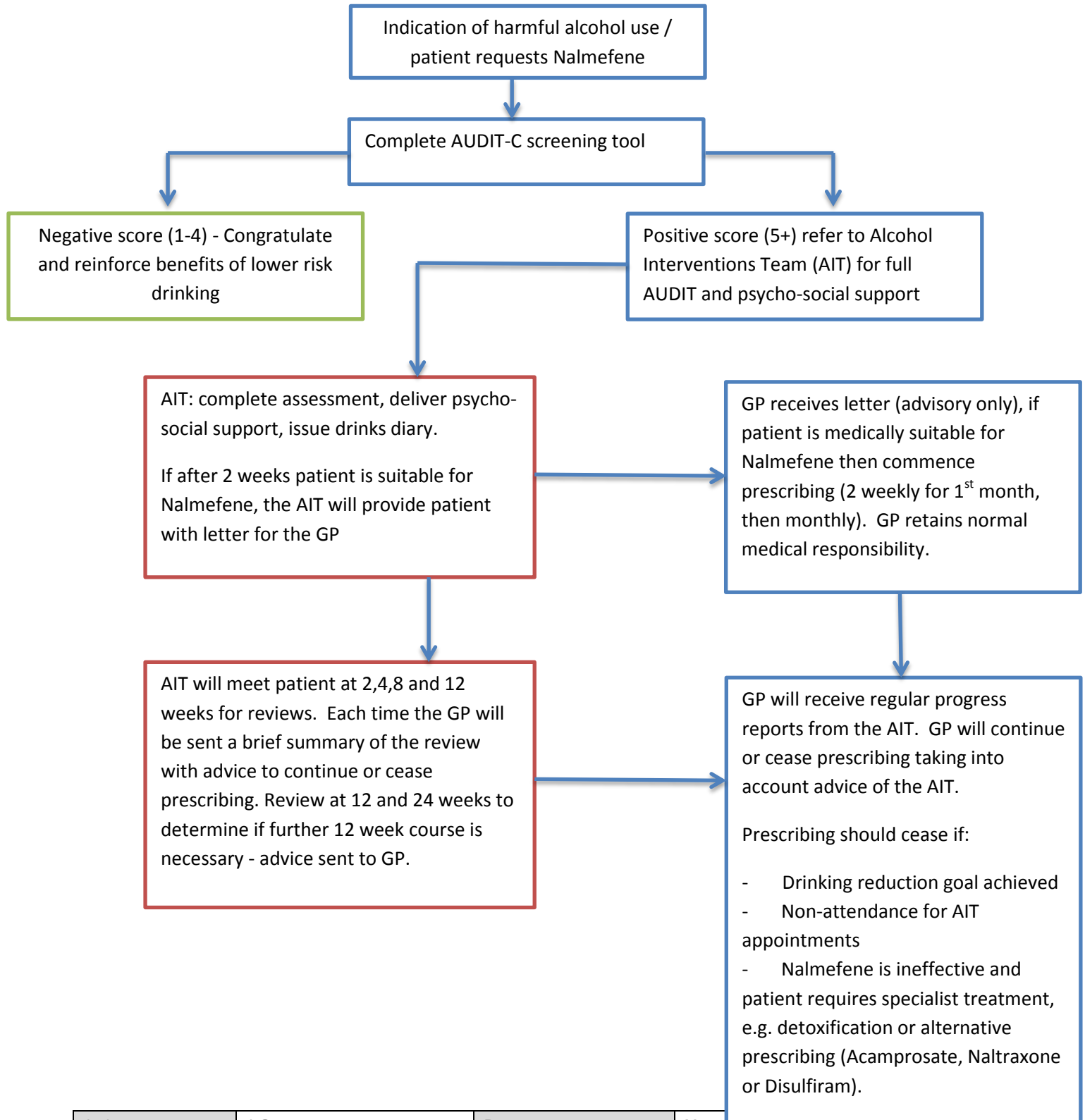
Adapted from: Lundbeck Prescribing Information, Date of last revision: August 2013

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|-----------|--------------------------|-------------|----------|
| Author | A Scott | Date | May 2015 |
| Job Title | Commissioning Pharmacist | Review Date | May 2018 |
| Version | 1.0 | 6 of 9 | |

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Appendix B

Shortened Nalmefene Pathway (GP version)



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|-----------|--------------------------|-------------|----------|
| Author | A Scott | Date | May 2015 |
| Job Title | Commissioning Pharmacist | Review Date | May 2018 |
| Version | 1.0 | 7 of 9 | |

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Appendix C Screening Tool (Nalmefene version)



The following questions are validated as screening tools for alcohol use

| AUDIT- C Questions | Scoring system | | | | | Your score |
|--|----------------|-------------------|---------------------|--------------------|-----------------------|----------------------|
| | 0 | 1 | 2 | 3 | 4 | |
| How often do you have a drink containing alcohol? | Never | Monthly or less | 2-4 times per month | 2-3 times per week | 4+ times per week | |
| How many units of alcohol do you drink on a typical day when you are drinking? | 1 -2 | 3-4 | 5-6 | 7-9 | 10+ | |
| How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year? | Never | Less than monthly | Monthly | Weekly | Daily or almost daily | |
| TOTAL : | | | | | | <input type="text"/> |

A score of **less than 5** indicates *lower risk drinking* (see overleaf)

Scores of 5+ offer referral to the **Alcohol Interventions Team**, or complete the following 7 questions:

| AUDIT Questions (after completing 3 AUDIT-C questions above) | Scoring system | | | | | Your score |
|--|----------------|-------------------|-------------------------------|--------|---------------------------|----------------------|
| | 0 | 1 | 2 | 3 | 4 | |
| How often during the last year have you found that you were not able to stop drinking once you had started? | Never | Less than monthly | Monthly | Weekly | Daily or almost daily | |
| How often during the last year have you failed to do what was normally expected from you because of your drinking? | Never | Less than monthly | Monthly | Weekly | Daily or almost daily | |
| How often during the last year have you needed an alcoholic drink in the morning to get yourself going after a heavy drinking session? | Never | Less than monthly | Monthly | Weekly | Daily or almost daily | |
| How often during the last year have you had a feeling of guilt or remorse after drinking? | Never | Less than monthly | Monthly | Weekly | Daily or almost daily | |
| How often during the last year have you been unable to remember what happened the night before because you had been drinking? | Never | Less than monthly | Monthly | Weekly | Daily or almost daily | |
| Have you or somebody else been injured as a result of your drinking? | No | | Yes, but not in the last year | | Yes, during the last year | |
| Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested that you cut down? | No | | Yes, but not in the last year | | Yes, during the last year | |
| TOTAL | | | | | | <input type="text"/> |

PLEASE TURN OVER for scoring & next steps >>>>>>

| | | | |
|-----------|--------------------------|-------------|----------|
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| Version | 1.0 | 8 of 9 | |

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Appendix D Drinks diary

| Day | Type of drink | Number of drinks | Units in the drink | Total units for day |
|---|--|----------------------|----------------------|---------------------|
| <i>Example:</i> | <i>Pint of lower strength lager</i> <i>Vodka and coke</i> | <i>1</i> <i>1</i> | <i>2</i> <i>1</i> | <i>3</i> |
| Monday | | | | |
| Tuesday | | | | |
| Wednesday | | | | |
| Thursday | | | | |
| Friday | | | | |
| Saturday | | | | |
| Sunday | | | | |
| <p>If do you find you are over the recommended limits, you may well want to start cutting back. Recommended limits are:</p> <ul style="list-style-type: none"> Men, no more than 3-4 units a day on a regular basis¹ Women, no more than 2-3 units a day on a regular basis¹, unless pregnant or trying to conceive² <p>¹ 'Regularly' means drinking every day or most days of the week. You should also take a break for 48 hours after a heavy drinking session to let your body recover. ² If you are pregnant or trying to conceive, it is recommended that you avoid drinking alcohol. But if you drink alcohol, it should be no more than 1-2 units once or twice a week and avoid getting drunk</p> | | Total | | |
| | | Daily Average | | |

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|-----------|--------------------------|-------------|----------|
| Author | A Scott | Date | May 2015 |
| Job Title | Commissioning Pharmacist | Review Date | May 2018 |
| Version | 1.0 | 9 of 9 | |

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