Interface Prescribing Subgroup
NALMEFENE▼ FOR REDUCTION OF ALCOHOL CONSUMPTION IN ADULTS
INFORMATION FOR PRIMARY CARE

RAG List Status
Nalmefene is classified as a GREEN (in conjunction with specialist service) drug by the Greater Manchester Medicines Management Group.

Licensed Indications
Nalmefene is licensed for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.

NICE Guidance
NICE TA325 : Nalmefene is recommended by NICE as a possible treatment for people with alcohol dependence who:
- are still drinking more than 7.5 units per day (for men) and more than 5 units per day (for women) 2 weeks after an initial assessment and
- do not have physical withdrawal symptoms and
- do not need to either stop drinking straight away or stop drinking completely.

Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption.

When should GPs be asked to prescribe?
GP will only prescribe when:
- Continuous psychosocial support focused on treatment adherence and reducing alcohol consumption is in place and patient continues to have a high DRL two weeks after initial assessment.

GPs should not prescribe when:
- Physical withdrawal symptoms
- Patients require immediate detoxification
- Patient not receiving continuous psychosocial support

Preparations available
Nalmefene▼ 18mg tablets (Selincro®)

Dosage and Administration
Nalmefene is to be taken as-needed: on each day the patient perceives a risk of drinking alcohol, one tablet (18mg) should be taken, preferably 1-2 hours prior to the anticipated time of drinking. If the patient has started drinking alcohol without taking nalmefene, the patient should take one tablet as soon as possible.
The maximum dose of nalmefene is one tablet (18mg) per day. Nalmefene can be taken with or without food.
The film-coated tablet should be swallowed whole. The film-coated tablet should not be divided or crushed because nalmefene may cause skin sensitisation when in direct contact with the skin.

Quantity to Prescribe
Prescribe 14 tablets per prescription as NICE predicts that patients will use nalmefene on 50% of days each month. It is recommended that this prescribing is maintained as an “acute” prescription on a monthly basis.

Dose Modifications

Renal Impairment	Hepatic Impairment
No dose adjustment is recommended for patients with mild or moderate renal impairment	No dose adjustment is recommended for patients with mild or moderate renal impairment

Contraindications
- Hypersensitivity to the active substance or to any of the excipients listed (refer to SPC).
- Patients taking opioid agonists (such as opioid analgesics, opioids for substitution therapy with opioid agonists (e.g. methadone) or partial agonists (e.g. buprenorphine))
- Patients with current or recent opioid addiction
- Patients with acute symptoms of opioid withdrawal
- Patients for whom recent use of opioids is suspected
- Patients with severe hepatic impairment (Child-Pugh classification)

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- Patients with severe renal impairment (eGFR <30 ml/min per 1.73 m2)
- Patients with a recent history of acute alcohol withdrawal syndrome (including hallucinations, seizures, and delirium tremens).
- Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption (medicine contains lactose).
- Pregnant or breastfeeding patient.

Cautions

- Opioid administration (see SPC for further information).
- Psychiatric effects were reported in clinical studies. If patients develop psychiatric symptoms that are not associated with treatment initiation with nalmefene, and/or that are not transient, the prescriber should consider alternative causes of the symptoms and assess the need for continuing treatment with Nalmefene.
- Nalmefene has not been investigated in patients with unstable psychiatric disease. Caution should be exercised if Nalmefene is prescribed to patients with current psychiatric comorbidity such as major depressive disorder.
- Seizure disorders - there is limited experience in patients with a history of seizure disorders, including alcohol withdrawal seizures. Caution is advised if treatment aimed at reduction of alcohol consumption is started in such patients.
- Elderly patients (≥65 years of age) – limited clinical data are available on the use of Nalmefene in patients ≥65 years of age with alcohol dependence

What are the main side-effects?

Nausea, vomiting, dry mouth, weight loss, decreased appetite, tachycardia, palpitation, dizziness, headache, somnolence, tremor, disturbance in attention, paraesthesia, hypoaesthesia, malaise, sleep disorders, confusion, restlessness, decreased libido, muscle spasms, hyperhidrosis. Hallucinations and dissociation also reported.
Nalmefene may have minor to moderate influence on the ability to drive and use machines and patients should exercise caution particular when starting treatment.

Drug Interactions

Co-administration with medicinal products that are potent inhibitors of the UGT2B7 enzyme (for example, diclofenac, fluconazole, medroxyprogesterone acetate, meclofenamic acid) may significantly increase the exposure to nalmefene. This is unlikely to present a problem with occasional use, but if long-term concurrent treatment with a potent UGT2B7 inhibitor is initiated, a potential for an increase in nalmefene exposure cannot be excluded.
Conversely, concomitant administration with a UGT inducer (for example, dexamethasone, phenobarbital, rifampicin, omeprazole) may potentially lead to subtherapeutic nalmefene plasma concentrations.
If nalmefene is taken concomitantly with opioid agonists (for example, certain types of cough and cold medicinal products, certain antidiarrhoeal medicinal products, and opioid analgesics), the patient may not benefit from the opioid agonist.
Simultaneous intake of alcohol and nalmefene does not prevent the intoxicating effects of alcohol.

Monitoring

GP to monitor patient at monthly intervals for adverse effects, adherence treatment, attendance at psychosocial support, and reduction in alcohol consumption.
GP is also advised to check renal and hepatic function on initiation of treatment.

When should the drug be stopped?

Treatment to be terminated by GP in consultation with specialist service providing psychosocial support.

- NICE guidance does not include clear information about when treatment should be stopped. Clinical data for the use of nalmefene under randomised controlled conditions are available for a period of 6 to 12 months. Prescribing should continue for no longer than 6 months, in line with the current evidence base.
- During treatment, the GP and specialist service should continue to assess the patient's progress in reducing alcohol consumption, overall functioning, treatment adherence, and any potential side effects.
- If patient stops receiving continuous psychosocial support the drug should be stopped.

References

GMMMG New Therapies Subgroup Position Statement on use of Nalmefene:
http://gmmmg.nhs.uk/docs/nts/NTS%20Nalmefene%20for%20alcohol%20dependence%20position%20statement.pdf

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