



July 2017

Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients.

The recommendation of this subgroup is as follows:*

Drug/Indication	Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients.
Recommendation	<p>The GMMMG FMESG recommends the use of sodium oxybate in adult patients whom have received and benefited from treatment with sodium oxybate as commissioned by NHS England. i.e. continuing treatment for those >19 years old.</p> <p>The NHS England criteria for starting and stopping must continue to be followed.</p> <p>The use of sodium oxybate in <u>new adult</u> patients is not recommended.</p>
Clinical Trial Data – Efficacy	<p>A meta-analysis and systematic review published in 2012 summarises all of the available randomised controlled trial evidence. The analysis demonstrates significant improvements in number of cataplexy attacks, wakefulness, number of sleep attacks and global clinician global impression of change associated with sodium oxybate against placebo.</p> <p>However, there are several limitations to the studies:</p> <ul style="list-style-type: none"> • Sample sizes for some comparisons were very small, • Confidence intervals were wide in several cases, limiting the precision of these estimates of treatment effect. • Short duration of trials. • Majority of data showing benefit for sodium oxybate was derived from trials against placebo. • Data on quality of life is lacking.
Clinical Trial Data – Safety	<p>Adverse effects including gastrointestinal effects, dizziness and enuresis were more common with sodium oxybate than placebo. Discontinuation due to adverse effects occurred in 7-9% of patients</p> <p>Sodium oxybate has the potential to induce respiratory depression.</p> <p>There is a potential for abuse of sodium oxybate.</p>

Cost Effectiveness/ Affordability	<p>No cost-effectiveness studies were found. The number of patients eligible for treatment with sodium oxybate is expected to be low. NHS England estimates that there are currently 10 children treated with sodium oxybate nationally.</p> <p>The cost of sodium oxybate varies with the dose, which ranges from 4.5 g to 9g daily. This results in an estimated cost per patient of £6,500 to £13,100 per year. Mean doses used in practice are likely to be in the middle of that range.</p> <p>Sodium oxybate is currently protected by several active patents; however generics are expected to enter the market in Europe starting in January 2020 which may alter costs.</p>
Patient perspective	<p>Narcolepsy is a disabling sleep disorder characterised by excessive daytime sleepiness. Patients are often unable to stay awake or asleep for long periods of time. This recommendation means that children and young people who have shown benefit from sodium oxybate therapy will be able to continue this treatment into adulthood.</p>

*** This recommendation is valid unless it has been superseded by a NICE TA or national guidance. The recommendation will only be reviewed when there is substantial new data that may change the initial recommendation. For recommendations that are >24 months old please note that there may be new data available and this should be checked prior to prescribing.*

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

References available on request.