Xyrem® (sodium oxybate)

Important risk minimisation information for Healthcare Professionals: Xyrem® (sodium oxybate) Treatment Initiation and Follow-Up Visit Form

This treatment initiation form is essential to ensure the safe and effective use of Xyrem® and the appropriate management of the important risks.

Please complete all sections of this form, sign and date and retain in your patient's medical records.

Please also review the Summary of Product Characteristics for complete information about this product.

For further supplies of this form and the patient-aimed educational materials provided, please contact UCB Pharma at:
UCBCares.IE@ucb.com; Tel: +353 1 4632371 (Ireland);
UCBCares.UK@ucb.com; Tel: +44(0)1753 777100 (UK)

Name of Patient .....

	CRITERIA TO ENSURE SAFE USE
1.	**Verify patient meets criteria for appropriate use of Xyrem®** ☐ Diagnosis of narcolepsy with cataplexy ☐ Age 7 or older ☐ Body weight >15kg ☐ No history of major depression ☐ No history of succinic semialdehyde dehydrogenase deficiency ☐ No current use of opioids or barbiturates
2.	**Assess whether any of the following apply to your patient and whether Xyrem® use is appropriate** ☐ Any history of drug abuse (Xyrem® has the potential for abuse and dependence) ☐ Additional risks of respiratory depression, including sleep apnoea ☐ Underlying respiratory disorder ☐ BMI ≥40 kg/m² ☐ Previous history of affective disorders (including depressive illness, anxiety and bipolar disorder), suicide attempt and psychosis, particularly amongst children and adolescents. These patients should be monitored particularly carefully for emergence of depressive symptoms and/or suicidal ideation ☐ History of seizures
3.	**Review patient's concomitant medications and adjust as necessary** ☐ Sedative hypnotics ☐ Antidepressants ☐ Modafinil ☐ Medicines that increase central nervous system activity ☐ Other drugs that are metabolized by GHB dehydrogenase such as valproate, phenytoin or ethosuximide ☐ Topiramate
4.	**Counsel patient/caregiver on the following and the need to seek medical advice where appropriate:** ☐ Importance of abstaining from alcohol use ☐ Because food significantly reduces the bioavailability of sodium oxybate, patients should eat at least several (2-3) hours before taking the first dose at bedtime. Patients should always observe the same timing of dosing in relation to meals ☐ Symptoms of respiratory depression ☐ Symptoms of depression/suicidality ☐ The emergence of thought disorders including thoughts of committing violent acts (including harming others) and/or behavioural abnormalities requires careful and immediate evaluation ☐ The potential for Xyrem® to cause seizures ☐ CNS effects and that Xyrem® will severely impair ability to drive and use machines
5.	**Explain conditions of safe storage of Xyrem®** ☐ Keep out of reach of children ☐ Do not share or sell Xyrem®
6.	**Instruct patient on:** ☐ Proper dosing and use of the dosing syringe provided in the Xyrem® pack
7.	**Provide the patient/caregiver with educational materials, as relevant** ☐ Patient Alert Card ☐ Patient Instructions for Administration of Sodium Oxybate ☐ Frequently Asked Questions for Patients ☐ Guide for Paediatric Patients and Caregivers

I confirm I have checked all the above items prior to the patient commencing Xyrem®

Name of Physician/Healthcare Professional _____

Signature _____ Date _____

For reporting of any adverse events, please refer to information shown on the reverse of this leaflet.

FOLLOW-UP VISIT

Patient Name:

Date of Visit:

✓	CRITERIA TO ENSURE CORRECT USE
☐	Assess and encourage patient to take Xyrem® as prescribed and using only the syringe provided in the Xyrem® pack • Appropriateness of dosage
☐	Review concomitant medications for changes that might cause drug-drug interactions
☐	Monitor for signs of abuse, misuse or diversion of Xyrem®
☐	Stress importance of abstaining from alcohol use
☐	Assess psychiatric behaviour
☐	Assess signs of respiratory depression
☐	Assess whether benefits of Xyrem® treatment continue to outweigh risks

CHECK-LIST SPECIFIC TO PAEDIATRIC PATIENTS

During titration period, 1 to 2 weeks before next up titration

☐ Monitor body weight ☐ Monitor respiratory function ☐ Monitor CNS function

☐	Assess height and weight, and whether there are any growth disorders (weight and height disorders)
☐	Assess posology according to SmPC
☐	Assess social behaviour (Behavior disorders, Communication issues, Educational difficulties)
☐	Assess psychiatric behaviour (Depression, Suicidal ideation, Psychosis, Cognitive disorders)
☐	Assess learning performance (School performance, Learning difficulties, Inability to perform tasks, Concentration/ attention difficulties, Memory issues)

Reporting adverse events after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. An adverse event can be anything from enuresis to under achievement in school.

Healthcare professionals are asked to report any adverse events. (Please refer to Reporting Adverse Reactions section for more information.)

UK & Ireland Specific Information

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
UK:
Healthcare professionals are asked to report any suspected adverse reactions via http://yellowcard.mhra.gov.uk/
Ireland:
Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance.
Website: www.hpra.ie.
Please also report Adverse Events to UCB Pharma at UCBCares: +44(0) 1753 777100;
Email: UCBCares.UK@ucb.com (UK) or + 353 1463 2371 Email: UCBCares.IE@ucb.com (Ireland)