

Sodium oxybate

Important risk minimisation information for Healthcare Professionals: Sodium oxybate Treatment Initiation and Follow-Up Visit Form

This treatment initiation form is essential to ensure the safe and effective use of Sodium oxybate 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:

Distributor

Marketing Authorisation Holder AS KALCEKS

E-mail: kalceks@kalceks.lv

Tel.: +371 67083320

Name of Patient

CRITERIA TO ENSURE SAFE USE	
1.	Verify patient meets criteria for appropriate use of Sodium oxybate <input type="checkbox"/> Diagnosis of narcolepsy with cataplexy <input type="checkbox"/> Age 18 or older <input type="checkbox"/> No history of major depression <input type="checkbox"/> No history of succinic semialdehyde dehydrogenase deficiency <input type="checkbox"/> No current use of opioids or barbiturates
2.	Assess whether any of the following apply to your patient and whether Sodium oxybate use is appropriate <input type="checkbox"/> Any history of drug or alcohol abuse (Sodium oxybate has the potential for abuse and dependence) <input type="checkbox"/> Additional risks of respiratory depression <input type="checkbox"/> Any history of sleep-related breathing disorders <input type="checkbox"/> Underlying respiratory disorder <input type="checkbox"/> BMI \geq 40 kg/m ² <input type="checkbox"/> Previous history of depression (depression/suicidality is a risk associated with Sodium oxybate use) <input type="checkbox"/> History of seizures
3.	Review patient's concomitant medications and adjust as necessary <input type="checkbox"/> Sedative hypnotics <input type="checkbox"/> Antidepressants <input type="checkbox"/> Modafinil <input type="checkbox"/> Medicines that increase central nervous system activity <input type="checkbox"/> Other drugs that are metabolized by GHB dehydrogenase such as valproate, phenytoin or ethosuximide <input type="checkbox"/> Topiramate
4.	Counsel patient on the following and the need to seek medical advice where appropriate: <input type="checkbox"/> Importance of abstaining from alcohol use <input type="checkbox"/> 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. <input type="checkbox"/> Symptoms of respiratory depression <input type="checkbox"/> Symptoms of depression/suicidality <input type="checkbox"/> The emergence of thought disorders including thoughts of committing violent acts (including harming others) and/or behavioural abnormalities requires careful and immediate evaluation <input type="checkbox"/> The potential for Sodium oxybate to cause seizures <input type="checkbox"/> CNS effects and that Sodium oxybate will severely impair ability to drive and use machines <input type="checkbox"/> The risk of abuse and misuse
5.	Explain conditions of safe storage of Sodium oxybate <input type="checkbox"/> Keep out of reach of children <input type="checkbox"/> Do not share or sell Sodium oxybate
6.	Instruct patient on: <input type="checkbox"/> Proper dosing and use of the dosing syringe
7.	Provide the patient with educational materials <input type="checkbox"/> Patient Alert Card <input type="checkbox"/> Frequently Asked Questions patients may have about the safety of Sodium oxybate <input type="checkbox"/> Dosing and Administration Brochure

I confirm I have checked all of the above items prior to the patient commencing Sodium oxybate

Name of Physician/Healthcare Professional

Signature Date

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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie. Requests to report all potential serious adverse events to AS Kalceks, e-mail: vigilance@grindeks.lv.

FOLLOW-UP VISIT
Patient Name:
Date of Visit:
✓ CRITERIA TO ENSURE SAFE USE
<input type="checkbox"/> Assess and encourage patient to take Sodium oxybate as prescribed • Appropriateness of dosage
<input type="checkbox"/> Review concomitant medications for changes that might cause drug-drug interactions
<input type="checkbox"/> Monitor for signs of abuse, misuse or diversion of Sodium oxybate
<input type="checkbox"/> Stress importance of abstaining from alcohol use
<input type="checkbox"/> Assess whether benefits of Sodium oxybate treatment continue to outweigh risks

-Tear off-

FOLLOW-UP VISIT
Patient Name:
Date of Visit:
✓ CRITERIA TO ENSURE SAFE USE
<input type="checkbox"/> Assess and encourage patient to take Sodium oxybate as prescribed • Appropriateness of dosage
<input type="checkbox"/> Review concomitant medications for changes that might cause drug-drug interactions
<input type="checkbox"/> Monitor for signs of abuse, misuse or diversion of Sodium oxybate
<input type="checkbox"/> Stress importance of abstaining from alcohol use
<input type="checkbox"/> Assess whether benefits of Sodium oxybate treatment continue to outweigh risks

-Tear off-

FOLLOW-UP VISIT
Patient Name:
Date of Visit:
✓ CRITERIA TO ENSURE SAFE USE
<input type="checkbox"/> Assess and encourage patient to take Sodium oxybate as prescribed • Appropriateness of dosage
<input type="checkbox"/> Review concomitant medications for changes that might cause drug-drug interactions
<input type="checkbox"/> Monitor for signs of abuse, misuse or diversion of Sodium oxybate
<input type="checkbox"/> Stress importance of abstaining from alcohol use
<input type="checkbox"/> Assess whether benefits of Sodium oxybate treatment continue to outweigh risks

FOLLOW-UP VISIT
Patient Name:
Date of Visit:
✓ CRITERIA TO ENSURE SAFE USE
<input type="checkbox"/> Assess and encourage patient to take Sodium oxybate as prescribed • Appropriateness of dosage
<input type="checkbox"/> Review concomitant medications for changes that might cause drug-drug interactions
<input type="checkbox"/> Monitor for signs of abuse, misuse or diversion of Sodium oxybate
<input type="checkbox"/> Stress importance of abstaining from alcohol use
<input type="checkbox"/> Assess whether benefits of Sodium oxybate treatment continue to outweigh risks

-Tear off-

FOLLOW-UP VISIT
Patient Name:
Date of Visit:
✓ CRITERIA TO ENSURE SAFE USE
<input type="checkbox"/> Assess and encourage patient to take Sodium oxybate as prescribed • Appropriateness of dosage
<input type="checkbox"/> Review concomitant medications for changes that might cause drug-drug interactions
<input type="checkbox"/> Monitor for signs of abuse, misuse or diversion of Sodium oxybate
<input type="checkbox"/> Stress importance of abstaining from alcohol use
<input type="checkbox"/> Assess whether benefits of Sodium oxybate treatment continue to outweigh risks

-Tear off-

FOLLOW-UP VISIT
Patient Name:
Date of Visit:
✓ CRITERIA TO ENSURE SAFE USE
<input type="checkbox"/> Assess and encourage patient to take Sodium oxybate as prescribed • Appropriateness of dosage
<input type="checkbox"/> Review concomitant medications for changes that might cause drug-drug interactions
<input type="checkbox"/> Monitor for signs of abuse, misuse or diversion of Sodium oxybate
<input type="checkbox"/> Stress importance of abstaining from alcohol use
<input type="checkbox"/> Assess whether benefits of Sodium oxybate treatment continue to outweigh risks