

Part VI: Summary of the risk management plan

Summary of risk management plan for Sodium Oxybate 500 mg/ml oral solution (sodium oxybate)

This is a summary of the risk management plan (RMP) for Sodium Oxybate 500 mg/ml oral solution. The RMP details important risks of Sodium Oxybate 500 mg/ml oral solution, how these risks can be minimised, and how more information will be obtained about Sodium Oxybate 500 mg/ml oral solution's risks and uncertainties (missing information).

Sodium Oxybate 500 mg/ml oral solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sodium Oxybate 500 mg/ml oral solution should be used.

Important new concerns or changes to the current ones will be included in updates of Sodium Oxybate 500 mg/ml oral solution's RMP.

I. The medicine and what it is used for

Sodium Oxybate 500 mg/ml oral solution is indicated for the treatment of narcolepsy with cataplexy in adult patients, adolescents and children from the age of 7 years (see SmPC for the full indication). It contains sodium oxybate as the active substance and it is given by oral administration in a concentration of 500 mg/mL supplied in 200 mL bottles containing 180mL of oral solution.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Sodium Oxybate 500 mg/ml oral solution, together with measures to minimise such risks and the proposed studies for learning more about Sodium Oxybate 500 mg/ml oral solution's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size – the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status – the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Sodium Oxybate 500 mg/ml oral solution, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Sodium Oxybate 500 mg/ml oral solution is not yet available, it is listed under “missing information” below.

II.A List of important risks and missing information

Important risks of Sodium Oxybate 500 mg/ml oral solution are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Sodium Oxybate 500 mg/ml oral solution. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	Overdose
	Respiratory depression
	CNS depression
	Depression/suicidality
	Convulsions
	Misuse/Abuse
	Dependence/withdrawal
	Diversion/criminal use
	Alcohol interaction
	Psychosis
Important potential risks	None
Missing Information	Long-term impact on children and adolescents, including growth and neurocognitive development

II.B Summary of important risks

Important identified risk: Alcohol interaction	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.4 and 4.5. PIL Section 2. Prescription-only medicine.

Important identified risk: Alcohol interaction	
	Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card).

Important identified risk: Overdose	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2, 4.4 and 4.9. PIL Section 3. Prescription-only medicine. Update to the syringe to add new graduations of 0.5 and 1.0 g below the current markings.
	Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card). Controlled distribution system.

Important identified risk: Respiratory depression	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2, 4.3, 4.4, 4.5, 4.8 and 4.9. PIL Sections 2 and 4. Prescription-only medicine. Update to the syringe to add new graduations of 0.5 and 1.0 g below the current markings
	Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card).

Important identified risk: CNS Depression	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2, 4.3, 4.4, 4.5, 4.7, 4.8 and 4.9. PIL Sections 2 and 4. Prescription-only medicine. Update to the syringe to add new graduations of 0.5 and 1.0 g below the current markings. Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card).

Important identified risks: Depression/suicidality	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.3, 4.4 and 4.8. PIL Sections 2, 3 and 4. Prescription-only medicine. Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card).

Important identified risk: Convulsions	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2, 4.4, 4.8 and 4.9. PIL Sections 2 and 4. Prescription-only medicine. Update to the syringe to add new graduations of 0.5 and 1.0 g below the current markings. Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card).

Important identified risks: Misuse/abuse	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2, 4.3, 4.4 and 4.8 PIL Sections 2, 3 and 4. Prescription-only medicine. Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card). Controlled distribution system.

Important identified risks: Dependence/ withdrawal	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2, 4.4 and 4.8 PIL Sections 2, 3 and 4. Prescription-only medicine Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card). Controlled distribution system.

Important identified risks: Diversion/criminal use	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2 and 4.4. PIL Section 2. Prescription-only medicine. Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card). Controlled distribution system.

Important identified risk: Psychosis	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.4 and 4.8. PIL Section 2. Prescription-only medicine. Additional risk minimisation measures Educational materials (HCP Checklist, Frequently Asked Questions (FAQs) for patients, Patient instructions for administration of sodium oxybate, Guide for Pediatric Patients and Caregivers, and Patient Alert Card).

Missing information: Long-term impact on children and adolescents, including growth and neurocognitive development	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2, 4.4 and 4.8. PIL Section 2. Additional risk minimisation measures Educational materials (HCP Checklist and Guide for Pediatric Patients and Caregivers).

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Sodium Oxybate 500 mg/ml oral solution.

II.C.2. Other studies in post-authorization development plan

There are no studies required for Sodium Oxybate 500 mg/ml oral solution.