Summary of risk management plan for Sodium Oxybate Kalceks (sodium oxybate)

This is a summary of the risk management plan (RMP) for **Sodium Oxybate Kalceks**. The RMP details important risks of **Sodium Oxybate Kalceks**, how these risks can be minimised, and how more information will be obtained about risks and uncertainties (missing information) of **Sodium Oxybate Kalceks**.

Summary of product characteristics (SPC) of **Sodium Oxybate Kalceks** and its package leaflet give essential information to healthcare professionals and patients on how **Sodium Oxybate Kalceks** should be used.

I. The medicine and what it is used for

Sodium Oxybate Kalceks is authorised for treatment pf narcolepsy with cataplexe in adult patients. It contains sodium oxybate as the active substance and it is given orally; each ml of solution contains 500 mg of sodium oxybate.

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

Important risks of **Sodium Oxybate Kalceks**, together with measures to minimise such risks and the proposed studies for learning more about risks of **Sodium Oxybate Kalceks**, 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 SPC 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 Kalceks**, 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 Kalceks** 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 Kalceks** are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Kalceks**. 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	Aggravation of cardiac failure due to additional sodium load Fluid retention in patients with compromised renal function due to additional sodium load
Missing information	Use in pregnancy/lactation Use on children/adolescents Use in elderly Use in patients with BMI >40 kg/m2

II.B Summary of important risks

Important identified risk - Overdose	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.9 and PIL section 4 Medicinal product subject to restricted medical prescription Additional risk minimization measures: Educational material: Healthcare professional checklist; FAQ patient information sheet; How to take Sodium Oxybate brochure for patients; Patient alert card. Controlled distribution programme.
Important identified risk - Respiratory depression	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4, 4.5, 4.8 and 4.9 and PIL section 2 and 4 Medicinal product subject to restricted medical prescription Additional risk minimisation measures Educational material: Healthcare professional checklist; FAQ patient information sheet; Patient alert card.
Important identified risk - CNS depression	
Risk minimisation measures	Routine risk minimization measures: SPC section 4.4, 4.5 and 4.8 and PIL section 2 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: Educational material: Healthcare professional checklist; FAQ patient information sheet; Patient alert card.

Important identified risk - Depression/suicidality	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.3, 4.4 and 4.8 and PIL section 2 and 4 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: Educational material: Healthcare professional checklist; FAQ patient information sheet; Patient alert card.
Important identified risk - Convulsions	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.8 and PIL section 4 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: Educational material: Healthcare professional checklist; FAQ patient information sheet; Patient alert card.
Important identified risk - Misuse/Abuse/Dependence/Withdrawal/Diversion/Criminal use	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 and 4.8 and PIL section 2 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: Educational material: Healthcare professional checklist; FAQ patient information sheet; Patient alert card. Controlled distribution programme.
Important identified risk - Alcohol interaction	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 and 4.5 and PIL section 2 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: Educational material: Healthcare professional checklist; FAQ patient information sheet; Patient alert card.
Important identified risk - Psychosis	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 and 4.8 and PIL section 4 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: Educational material: Healthcare professional checklist; FAQ patient information sheet; Patient alert card.
Important potential risk- Aggravation of cardiac failure due to additional sodium load/Fluid retention in patients with compromised renal function due to additional sodium load	

Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2, 4.4 and PIL section 3 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: None
Missing information - Use in pregnancy/lactation	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.6 and PIL section 2 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: None
Missing information - Use in children/adolescents	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2 and PIL section 2 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: None
Missing information - Use in elderly	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2, 4.4 and PIL section 2 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: None
Missing information - Use in patients with BMI >40 kg/m2	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 Medicinal product subject to restricted medical prescription Additional risk minimisation measures: None

II.C *Post-authorisation development plan*

Not applicable.