13 Part VI: Summary of the risk management plan (RMP) – Sugammadex sodium, 200 mg/2 ml, 500 mg/5 ml, Solution for Injection

This is a summary of the RMP for Sugammadex sodium, 200 mg/2 ml, 500 mg/5 ml, Solution for Injection. The RMP details important risks of Sugammadex sodium Solution for Injection, how these risks can be minimized, and how more information will be obtained about Sugammadex sodium Solution for Injection' risks and uncertainties (missing information).

Sugammadex sodium Solution for Injection summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how Sugammadex sodium should be used.

Important new concerns or changes to the current ones will be included in updates of the Sugammadex sodium Solution for Injection's RMP.

13.1 Part VI: I. The medicine and what it is used for

Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults.

For the pediatric population: Sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years.

It contains Sugammadex sodium as active substance and is administered intravenously as 200 mg/2 ml, 500 mg/5 ml, Solution for Injection.

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Sugammadex sodium Solution for Injection, together with measures to minimize such risks are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Reports (PSURs) assessment (if applicable) 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 Sugammadex sodium Solution for Injection is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of Sugammadex sodium Solution for Injection are risks that need special risk management activities to further investigate or minimize 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 Sugammadex sodium Solution for Injection. 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).

Table 13-1 List of important risks and missing information

Important identified risks	Delayed onset time or insufficient neuromuscular blockade at re-treatment with steroidal neuromuscular blocking agent
	Neuromuscular block prolonged (Delayed recovery)
	Re-occurrence of neuromuscular blockade
	Anesthetic complication/Light anesthesia
	Use of sugammadex in patients with renal impairment
Important potential risks	Drug hypersensitivity
	Capturing interactions
	Displacement interactions
Missing information	Effect on values for laboratory parameters of blood coagulation time (aPTT, PT(inr), PT)
	Exposure in infants and neonates
	Exposure in pregnancy
	Excretion of sugammadex in human milk

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Sugammadex sodium Solution for Injection.

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

There are no studies required for Sugammadex sodium Solution for Injection.