Summary of risk management plan for Sugammadex Fresenius Kabi

This is a summary of the risk management plan (RMP) for Sugammadex Fresenius Kabi. The RMP details important risks of Sugammadex Fresenius Kabi, how these risks can be minimised, and how more information will be obtained about Sugammadex Fresenius Kabi's risks and uncertainties (missing information).

Sugammadex Fresenius Kabi's summary of product characteristics (SmPC) and its package leaflet (PL) gives essential information to healthcare professionals and patients on how the drug should be used.

This summary of the RMP for Sugammadex Fresenius Kabi should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Sugammadex Fresenius Kabi's RMP.

I. The medicine and what it is used for

Therapeutic Indications

- Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults.
- For the paediatric 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 should be administered intravenously as a single bolus injection.

Further information about the evaluation of Sugammadex Fresenius Kabi's benefits can be found in Sugammadex Fresenius Kabi's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/sugammadex-fresenius-kabi

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

Important risks of Sugammadex Fresenius Kabi, together with measures to minimise such risks and the proposed studies for learning more about Sugammadex Fresenius Kabi'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 PL and RSI 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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Sugammadex Fresenius Kabi are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered via infusion.
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 Fresenius Kabi. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

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

II.C Post-authorisation 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 Sugammadex Fresenius Kabi.

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

There are no studies required for Sugammadex Fresenius Kabi.