PART VI: Summary of the risk management plan

Summary of risk management plan for Sugammadex 100 mg/ml solution for injection (Sugammadex)

This is a summary of the risk management plan (RMP) for Sugammadex 100 mg/ml solution for injection. The RMP details important risks of Sugammadex 100 mg/ml solution for injection, and how more information will be obtained about Sugammadex 100 mg/ml solution for injection's risks and uncertainties (missing information).

Sugammadex 100 mg/ml solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sugammadex 100 mg/ml solution for injection should be used.

I. The medicine and what is used for

Sugammadex 100 mg/ml solution for injection is authorised for the treatment of reversal neuromuscular blockade induced by rocuronium or vecuronium in adults. For paediatric population, sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years (see SmPC for the full indication). It contains Sugammadex as the active substance, and it is administered intravenously as a single bolus injection.

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

Important risks of Sugammadex 100 mg/ml solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Sugammadex 100 mg/ml solution for injection are outlined below.
Measures to minimise the risks identified for medicinal are:

- Specific information: warnings, precautions, and advice on correct use in the package leaflet and SmPC of the product 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 of Sugammadex 100 mg/ml solution for injection is a medicinal product subject to medical prescription

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***.

If important information that may affect the safe use of Sugammadex 100 mg/ml solution for injection is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sugammadex 100 mg/ml solution for injection 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 Sugammadex 100 mg/ml 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);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing Information	None

II.B Summary of important risks

There are no important risks for Sugammadex 100 mg/ml solution for injection.

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 authorization or specific obligation of Sugammadex 100 mg/ml solution for injection.

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

There are no studies required for Sugammadex 100 mg/ml solution for injection.