PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Sugammadex Mylan (Sugammadex)

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

Sugammadex Mylan 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for Sugammadex Mylan should be read in the context of all the 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 Mylan's RMP.

I. The medicine and what it is used for

Sugammadex Mylan is authorised for 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 as the active substance and it is given by intravenously as a single bolus injection.

Further information about the evaluation of sugammadex Mylan’s benefits can be found in Sugammadex Mylan’s EPAR, including in its plain-language summary, available on the EMA website (https://www.ema.europa.eu/en/medicines/human/EPAR/sugammadex-mylan).

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

Important risks of Sugammadex Mylan, together with measures to minimise such 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 minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events 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 Mylan is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of sugammadex Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to/taken by patients. 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 Mylan. 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/use in special patient populations etc.);

Part VI: Summary of safety concerns

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 • Slow recovery from neuromuscular blockade (Drug effect decreased) • Recurrence of neuromuscular blockade

List of important risks and missing information	
	• Use of sugammadex in patients with renal impairment; after re-treatment with a steroidal NMBA delayed onset of neuromuscular blockade may occur • Anaesthetic complication • Hypersensitivity, including anaphylaxis/anaphylactic shock • Bronchospasm in patients with a history of pulmonary complications • Bradycardia
Important potential risks	• Bleeding complications in patients with coagulopathy • Capturing interactions (hormonal contraceptives, drugs yet to be marketed and other unknown drugs), leading to reduced efficacy • Displacement interactions (fusidic acid, toremifene, drugs yet to be marketed and other unknown drugs), leading to reduced efficacy
Missing information	• Exposure in infants and neonates • Exposure during pregnancy • Exposure in human milk • Exposure in patients with hepatic impairment including hepatic impairment accompanied by coagulopathy

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 Mylan.

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

There are no studies required for Sugammadex Mylan.