Part VI: Summary of the risk management plan

Summary of risk management plan for Sugammadex beta 100 mg/ml Injektionslösung (sugammadex sodium)

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

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

Important new concerns or changes to the current ones will be included in updates of Sugammadex beta 100 mg/ml Injektionslösung's RMP.

I. The medicine and what it is used for

Sugammadex beta 100 mg/ml Injektionslösung 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 (see SmPC for the full indications). It contains sugammadex sodium as the active substance and it is given intravenously.

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

Important risks of Sugammadex beta 100 mg/ml Injektionslösung, together with measures to minimise such risks and the proposed studies for learning more about Sugammadex beta 100 mg/ml Injektionslösung'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 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* 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 beta 100 mg/ml Injektionslösung is not yet available, it is listed under 'missing information' below

II.A List of important risks and missing information

Important risks of Sugammadex beta 100 mg/ml Injektionslösung are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 beta 100 mg/ml Injektionslösung. 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).

Summary of safety concerns	
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

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 beta 100 mg/ml Injektionslösung.

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

There are no studies required for Sugammadex beta 100 mg/ml Injektionslösung.