Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for sugammadex (Sugammadex 100 mg/mL solution for injection)

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

Sugammadex's Summary of Product Characteristics (SmPC) and its Package Leaflet give essential information to healthcare professionals (HCP) and patients on how sugammadex should be used.

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

I. The Medicine and What it is Used for

Sugammadex is authorised for the routine reversal of neuromuscular blockade (NMB) in adults, children and adolescents. Refer to the SmPC for the full indication.

It contains sugammadex as the active substance and it is available as solution for injection (100 mg/mL) for administration as a single intravenous (IV) bolus at doses of 2 mg/kg, 4 mg/kg, and 16 mg/kg.

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's risks, are outlined here after.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the SmPC addressed to HCP;
- 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 HCP 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 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

Not applicable.

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.

II.C.2 Other Studies in Post-authorisation Development Plan

There are no studies required for sugammadex.