EU Risk Management Plan for Sugammadex Fresenius Kabi 100 mg/mL solution for injection

Sugammadex Fresenius Kabi 100 mg/mL solution for injection

RMP version to be assessed as part of this application:

RMP Version number	1.1
Data lock point for this RMP	01-March-2025
Date of final sign off	09-Apr-2025
Rationale for submitting an updated RMP	The RMP version (1.0) of Sugammadex Kabi is updated to harmonize with Reference Medicinal product (Bridion) with extension of the indication to paediatric patients (from birth to under 2 years of age).
Summary of significant changes in this RMP	The RMP is updated to extend the paediatric indication in the EU align with that of reference medicinal product (Bridion 100 mg/ml solution for injection, RMP v.9.0, dated 06-Dec-2024)
Other RMP versions under evaluation	RMP Version number: Not applicable
	Submitted on: Not applicable
	Procedure number: Not applicable
Details of the currently approved RMP	Version number: 1.0
	Approved with procedure: Centralised Procedure EMEA/H/C/005760
	Date of approval (opinion date): 15-July-2022

Deputy QPPV name	Ana Rita Barata
Deputy QPPV signature	[redacted]

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Part I: Product(s) Overview

Table Part I.1 – Product Overview

Active substance(s) **(INN or common name)**	Sugammadex Sodium
Pharmacotherapeutic group(s) (ATC Code)	All other therapeutic products, Antidotes ATC Code: V03AB35
Marketing Authorisation Holder or Applicant	Fresenius Kabi Deutschland GmbH, Else- Kroener-Strasse 1, 61352 Bad Homburg v.d.H., Germany
Medicinal products to which this RMP refers	01
Invented name(s) in the European Economic Area (EEA)	Sugammadex Fresenius Kabi 100 mg/mL solution for injection
Marketing authorisation procedure	Centralised Procedure
Brief description of the product	Chemical class: Modified Gamma Cyclodextrin
	Summary of mode of action: Sugammadex is a modified gamma cyclodextrin which is a Selective Relaxant Binding Agent. It forms a complex with the neuromuscular blocking agents rocuronium or vecuronium in plasma and thereby reduces the amount of neuromuscular blocking agent available to bind to nicotinic receptors in the neuromuscular junction. This results in the reversal of neuromuscular blockade induced by rocuronium or vecuronium.
	Important information about its composition: Not applicable
Hyperlink to the Product Information	For latest summary of product characteristics (SmPC) and package leaflet (PL) of Sugammadex Fresenius Kabi 100 mg/mL solution for injection, please refer section 1.3.1 of eCTD.
Indication(s) in the EEA	Current (if applicable): • 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 paediatric patients from birth to 17 years.
	Proposed (if applicable): Not applicable

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Dosage in the EEA	Current (if applicable): **Posology** Sugammadex should only be administered by, or under the supervision of an anaesthetist. The use of an appropriate neuromuscular monitoring technique is recommended to monitor the recovery of neuromuscular blockade. The recommended dose of sugammadex depends on the level of neuromuscular blockade to be reversed. The recommended dose does not depend on the anaesthetic regimen. Sugammadex can be used to reverse different levels of rocuronium or vecuronium induced neuromuscular blockade: *Adults* Routine reversal: A dose of 4 mg/kg sugammadex is recommended if recovery has reached at least 1-2 post tetanic counts (PTC) following rocuronium or vecuronium induced blockade. Median time to recovery of the T4/T1 ratio to 0.9 is around 3 minutes. A dose of 2 mg/kg sugammadex is recommended, if spontaneous recovery has occurred up to at least the reappearance of T2 following rocuronium or vecuronium induced blockade. Median time to recovery of the T4/T1 ratio to 0.9 is around 2 minutes. Using the recommended doses for routine reversal will result in a slightly faster median time to recovery of the T4/T1 ratio to 0.9 of rocuronium when compared to vecuronium induced neuromuscular blockade. Immediate reversal of rocuronium-induced blockade: If there is a clinical need for immediate reversal following administration of rocuronium a dose of 16 mg/kg sugammadex is recommended. When 16 mg/kg sugammadex is administered 3 minutes after a bolus dose of 1.2 mg/kg rocuronium bromide, a median time to recovery of the T4/T1 ratio to 0.9 of approximately 1.5 minutes can be expected. There is no data to recommend the use of sugammadex for immediate reversal following vecuronium induced blockade. Re-administration of sugammadex: In the exceptional situation of recurrence of neuromuscular blockade post-operatively after an initial dose of 2 mg/kg or 4 mg/kg sugammadex, a repeat dose of 4 mg/kg sugammadex is recommended.

	Following a second dose of sugammadex, the patient should be closely monitored to ascertain sustained return of neuromuscular function. **Method of administration** Sugammadex should be administered intravenously as a single bolus injection. The bolus injection should be given rapidly, within 10 seconds, into an existing intravenous line.
	Proposed (if applicable): Not applicable
Pharmaceutical form(s) and strengths	Current (if applicable): Sugammadex Fresenius Kabi 100 mg/mL solution for injection
	Proposed (if applicable): Not applicable
Is/will the product be subject to additional monitoring in the EU?	No

Part II: Safety specification

Part II: Module SI – Epidemiology of the indication(s) and target populations

Not applicable

Part II: Module SII – Non-clinical part of the safety specification

Not applicable

Part II: Module SIII – Clinical trial exposure

Not applicable

Part II: Module SIV – Populations not studied in clinical trials

Not applicable

Part II: Module SV - Post-authorisation experience

SV.1 Post-authorisation exposure

Not applicable.

Part II: Module SVI - Additional EU requirements for the safety specification

Not applicable

Part II: Module SVII - Identified and potential risks

The safety concerns of Sugammadex Fresenius Kabi 100 mg/mL solution for injection are based on the RMP of the reference medicinal product, Bridion 100 mg/ml solution for injection (RMP version 9.0, dated: 06-Dec-2024).

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Part II: Module SVIII - Summary of the safety concerns

Table SVIII.1: Summary of safety concerns

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

Part III: Pharmacovigilance Plan (including post-authorisation safety studies)

III.1 Routine pharmacovigilance activities

Fresenius Kabi has established an effective pharmacovigilance system to collect, collate and evaluate individual case safety reports obtained through spontaneous reporting systems, identified from the worldwide scientific literature or received from competent authorities. Individual case safety reports are followed up to ensure that all relevant information is captured. Cumulative safety information is regularly reviewed during signal detection processes.

Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:

Specific adverse reaction follow-up questionnaires:

Not applicable.

Other forms of routine pharmacovigilance activities:

Not applicable.

III.2 Additional pharmacovigilance activities

There are no planned, ongoing or completed additional pharmacovigilance activities.

III.3 Summary Table of additional Pharmacovigilance activities

There are no ongoing or planned categories 1-3 safety studies.

Part IV: Plans for post-authorisation efficacy studies

No imposed post-authorisation efficacy studies are on-going or planned.

Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

The safety information in the proposed product information is aligned to the reference medicinal product, Bridion 100 mg/ml solution for injection.

V.1. Routine Risk Minimisation Measures

Not applicable

V.2. Additional Risk Minimisation Measures

Not applicable

V.3. Summary of risk minimisation measures

Not applicable

Part VI: Summary of the risk management plan

Summary of risk management plan for Sugammadex Kabi 100 mg/mL solution for injection

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

Sugammadex Kabi 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 Kabi 100 mg/mL solution for injection should be used.

Important new concerns or changes to the current ones will be included in updates of Sugammadex Kabi 100 mg/mL solution for injection'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 paediatric patients from birth to 17 years.

It contains sugammadex sodium as active substance and should be 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 Kabi 100 mg/mL solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Sugammadex Kabi 100 mg/mL solution for injection'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 Kabi 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 Kabi 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

The safety information in the proposed product information is aligned to the reference medicinal product (Bridion 100 mg/ml solution for injection).

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 Kabi 100 mg/mL solution for injection.

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

There are no on-going or closed studies for Sugammadex Kabi 100 mg/mL solution for injection.

Part VII: Annexes

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Annex 1 – EudraVigilance Interface

Not applicable.

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable.

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable.

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable.

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable.

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable.

Annex 7 - Other supporting data (including referenced material)

Not applicable.

Annex 8 – Summary of changes to the risk management plan over time

Version	Approval date Procedure	Change
1.1	Centralised Procedure	The RMP is updated to extend the paediatric indication in the EU align with that of reference medicinal product (Bridion 100 mg/ml solution for injection, RMP v.9.0, dated 06-Dec-2024)
1.0	Approval date: 15-July-2022	Not applicable (First version of the RMP)

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	Procedure Number: EMEA/H/C/005760	