Swiss Summary of the Risk Management Plan (RMP)

for

Bridion®

(Sugammadex)

Solution for injection

Version 8.0 (November 2021)

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Bridion® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Bridion® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. MSD Merck Sharp & Dohme AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Bridion®.

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Summary of risk management plan for Bridion (sugammadex)

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 product information (see www.swissmedicinfo.ch) gives essential information to healthcare professionals and patients on how sugammadex should be used.

This summary of the RMP for Bridion should be read in the context of all this information.

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 product information 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 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 Bridon, together with measures to minimise such risks and the proposed studies for learning more about Bridion '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 product information;
- 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, including PSUR assessment 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 Bridion 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 Bridion. 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).

Table II.A.1: List of Important Risks and Missing Information

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 Routine Pharmacovigilance Activities

Routine Pharmacovigilance Activities Beyond Adverse Reactions Reporting and Signal Detection:

Not applicable

II.D Additional Pharmacovigilance Activities

There are no ongoing or planned additional pharmacovigilance studies that are required for sugammadex.

II.E Summary Table of Additional Pharmacovigilance Activities

Not applicable

II.F Risk Minimisation Plan

Not applicable

II.F.I Routine Risk Minimization Measures

Not applicable

II.F.II Additional Risk Minimization Measures

Not applicable

II.F.III Summary of Risk Minimization Measures

Not applicable

III. Post-Authorisation Development Plan

III.A Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of sugammadex.

III.B Other Studies in Post-Authorisation Development Plan

There are no studies required for sugammadex.

IV. Summary of Changes to the Swiss Risk Management Plan Summary Over Time

Major Changes to the Swiss Risk Management Plan Summary

RMP Summary Version	Date	Safety Concerns	Comment
8.0	November 2021	NA	Initial Version