

Summary of risk management plan for Sugammadex Adroiq (Sugammadex)

This is a summary of the risk management plan (RMP) for Sugammadex Adroiq 100mg/mL solution for injection. The RMP details important risks of Sugammadex, risk minimisation measures needed to minimise these risks and routine pharmacovigilance activities needed to obtain more information about Sugammadex Adroiq 100mg/mL solution for injection risks and uncertainties (missing information).

Sugammadex Adroiq 100mg/ml solution for injection summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sugammadex Adroiq 100mg/mL solution for injection should be used.

This summary of the RMP for Sugammadex Adroiq 100mg/mL solution for injection should be read in the context of all this 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 Adroiq 100mg/ml solution for injection 's RMP.

I. The medicine and what it is used for

Sugammadex Adroiq 100mg/ml solution for injection 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 IV bolus at doses of 2 mg/kg, 4 mg/kg and 16 mg/kg.

Further information about the evaluation of Sugammadex Adroiq 100mg/ml solution for injection s benefits can be found in Sugammadex Adroiq 100mg/ml solution for injection s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage. (<https://www.ema.europa.eu/en/medicines/human/EPAR/sugammadex-adroiq>).

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

Important risks of Sugammadex Adroiq 100mg/ml solution for injection together with measures to minimise such risks and the proposed studies for learning more about Sugammadex Adroiq 100mg/ml solution for injection 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 SmPC addressed to 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 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 periodic safety update report assessment so that prompt 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 Adroiq 100mg/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 Adroiq 100mg/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.

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.

II.C. Post-authorisation Development Plan

No post authorisation study is planned for this product.

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 Adroiq 100mg/ml solution for injection.

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

There are no studies required for Sugammadex Adroiq 100mg/ml solution for injection.