

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Sugammadex Aguettant

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

Sugammadex Aguettant's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sugammadex Aguettant should be used.

#### **I. The medicine and what it is used for**

Sugammadex Aguettant is authorised for reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults and for routine reversal of rocuronium induced blockade in children and adolescents aged from 2 to 17 years (see SmPC for the full indication). It contains sugammadex as the active substance and it is given by intravenous route.

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

Important risks of Sugammadex Aguettant, together with measures to minimise such risks and the proposed studies for learning more about Sugammadex Aguettant'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.

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 Sugammadex Aguettant 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 Aguettant. 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 1: List of important risks and missing information

<b>List of important risks and missing information</b>	
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 Aguettant.

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

There are no studies required for Sugammadex Aguettant

