

Part VI: Summary of the risk management plan

Summary of risk management plan for Rocuronium-hameln 10 mg/ml solution for injection / infusion

This is a summary of the risk management plan (RMP) for Rocuronium-hameln 10 mg/ml solution for injection / infusion. The RMP details important risks of Rocuronium-hameln 10 mg/ml solution for injection / infusion, how these risks can be minimised, and how more information will be obtained about Rocuronium-hameln 10 mg/ml solution for injection / infusion's risks and uncertainties (missing information).

Rocuronium-hameln 10 mg/ml solution for injection / infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rocuronium-hameln 10 mg/ml solution for injection / infusion should be used.

I. The medicine and what it is used for

Rocuronium-hameln 10 mg/ml solution for injection / infusion is authorised in adult and paediatric patients (from term neonates to adolescents (0 to < 18 years)) as an adjunct to general anaesthesia to facilitate tracheal intubation during routine sequence induction and to provide skeletal muscle relaxation during surgery. In adults rocuronium bromide is also indicated to facilitate tracheal intubation during rapid sequence induction and as an adjunct in the intensive care unit (ICU) (e.g. to facilitate intubation) for short term use. It contains rocuronium bromide as the active substance and it is given by injection and infusion.

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

Important risks of Rocuronium-hameln 10 mg/ml solution for injection / infusion, together with measures to minimise such risks and the proposed studies for learning more about Rocuronium-hameln 10 mg/ml solution for injection / infusion'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*.

If important information that may affect the safe use of Rocuronium-hameln 10 mg/ml solution for injection / infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rocuronium-hameln 10 mg/ml solution for injection / infusion 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 Rocuronium-hameln 10 mg/ml solution for injection / infusion. 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	<ul style="list-style-type: none">- Hypersensitivity reactions (including anaphylactic and anaphylactoid reaction)- Prolonged neuromuscular blockade- Long term use (e.g. myopathy, prolonged paralysis and/or skeletal muscle weakness)
Important potential risks	<ul style="list-style-type: none">- Kounis syndrome- Use in patients with hepatobiliary tract disorders- Use in patients with neuromuscular disorders
Missing information	<ul style="list-style-type: none">- Use in lactation

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

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 Rocuronium-hameln 10 mg/ml solution for injection / infusion.

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

There are no studies required for Rocuronium-hameln 10 mg/ml solution for injection / infusion.