Part VI: Summary of the risk management plan

Summary of risk management plan for Cisatracurium Accordpharma 2 mg/ml Solution for injection/infusion and Cisatracurium Accordpharma 5 mg/ml Solution for injection/infusion (cisatracurium besilate)

This is a summary of the risk management plan (RMP) for Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml solution for injection/infusion The RMP details important risks of Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml solution for injection/infusion, how these risks can be minimised, and how more information will be obtained about Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml solution for injection/infusion's risks and uncertainties (missing information).

Cisatracurium Accordpharma 2 mg/ml and 5 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 Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml Solution for injection/infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml solution for injection/infusion's RMP.

I. The medicine and what it is used for

Cisatracurium is indicated for use during surgical and other procedures in adults and children aged 1 month and over. Cisatracurium is also indicated for use in adults requiring intensive care. Cisatracurium can be used as an adjunct to general anaesthesia, or sedation in the Intensive Care Unit (ICU) to relax skeletal muscles, and to facilitate tracheal intubation and mechanical ventilation. It contains cisatracurium besilate as the active substance and it is given as intravenous bolus or infusion.

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

Important risks of Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml solution for injection/infusion, together with measures to minimise such risks and the proposed studies for

learning more about Cisatracurium Accordpharma 2 mg/ml and 5 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 (as required) and signal management activity, 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 Cisatracurium Accordpharma 2 mg/ml and 5 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 Cisatracurium Accordpharma 2 mg/ml and 5 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 taken. 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 Cisatracurium Accordpharma 2 mg/ml and 5 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).

Important Identified Risk	• Hypersensitivity to atracurium, cisatracurium or benzenesulfonic acid • Lack of ventilatory support • Patients with myasthenia gravis and other forms of neuromuscular diseases • Patients with severe acid-base or serum electrolyte abnormalities • Drug interactions • Administration into the infusion line of a blood transfusion
Important Potential Risk	• Nervous system disorders (e.g. seizures) • Musculoskeletal and connective tissue disorders (e.g. myopathy, muscle weakness)
Missing Information	• Use in neonates (aged less than 1 month) • Patients with serious cardiovascular disease • Patients suffering from burns • Pregnancy • Lactation • Carcinogenicity • Effects on fertility • Patients with a history of malignant hyperthermia • Patients undergoing surgery with induced hypothermia (25 to 28 °C) • Use in paediatric patients in the Intensive Care Unit

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 Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml solution for injection/infusion.

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

There are no studies required for Cisatracurium Accordpharma 2 mg/ml and 5 mg/ml solution for injection/infusion.