PART VI Summary of the risk management plan

Summary of risk management plan for Cisatracurium Kalceks (cisatracurium besilate)

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

Summary of product characteristics (SPC) of **Cisatracurium Kalceks** and its package leaflet give essential information to healthcare professionals and patients on how **Cisatracurium Kalceks** should be used.

I. The medicine and what it is used for

Cisatracurium Kalceks belongs to a group of medicines called muscle relaxants.

Cisatracurium Kalceks is used to relax muscles during surgical and other procedures in adults and children aged 1 month and over.

This product contains cisatracurium besilate as the active substance and it is administered as injection or infusion; 1 ml of solution contains 2 mg of cisatracurium (as cisatracurium besilate 2,68 mg); each ampoule of 2,5 ml of solution contains 5 mg of cisatracurium (as cisatracurium besilate 6,7 mg); each ampoule of 5 ml of solution contains 10 mg of cisatracurium (as cisatracurium besilate 13,4 mg); each ampoule of 10 ml of solution contains 20 mg of cisatracurium (as cisatracurium besilate 26,8 mg).

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

Important risks of **Cisatracurium Kalceks**, together with measures to minimise such risks and the proposed studies for learning more about risks of **Cisatracurium Kalceks**, 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 SPC 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.

II.A *List of important risks and missing information*

Important risks of **Cisatracurium Kalceks** 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 **Cisatracurium Kalceks**. 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 3 Summary of the RMP - List of important risks and missing information

Important identified risks	Hypersensitivity to atracurium, cisatracurium or benzenesulfonic acid Lack of ventilatory support Patients with myasthenia gravis and other forms of neuromuscular disease Patients with severe acid-base or serum electrolyte abnormalities Drug interactions Administration into the infusion line of a blood transfusion
Important potential risks	Nervous system disorder (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*

Not applicable.