Part VI: Summary of the risk management plan

Summary of risk management plan for Suxamethonium chloride Aguettant (Suxamethonium chloride)

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

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

I. The medicine and what it is used for

Suxamethonium chloride Aguettant is indicated as a muscle relaxant to facilitate endotracheal intubation during induction of general anesthesia or emergency situations, in adults and paediatric population above 2 years of age and with a body weight of at least 10 kg.

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

Important risks of Suxamethonium chloride Aguettant, together with measures to minimise such risks and the proposed studies for learning more about Suxamethonium chloride 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 in order 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 the case of Suxamethonium chloride Aguettant, these measures are not supplemented with *additional risk minimization measures*.
If important information that may affect the safe use of <invented name> is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Suxamethonium chloride 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 Suxamethonium chloride 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)

List of important risks and missing information	
Important identified risks	Hypersensitivity Hyperkalaemia Malignant hyperthermia Arrhythmia Use in patients with reduced activity or deficiency of plasma cholinesterase
Important potential risks	None
Missing information	Fertility Breastfeeding

Important identified risk: Hypersensitivity	
Evidence for linking the risk to the medicine	Information concerning hypersensitivity to suxamethonium is described in the literature
Risk factors and risk groups	Patients with a known history of hypersensitivity to suxamethonium. Because high rates of cross-sensitivity have been reported, patients with history of hypersensitivity reaction to any neuromuscular blocker.
Risk minimisation measures	Routine risk minimisation measures: - SmPC sections 4.3; 4.4; and 4.8. - Package leaflet sections 2; 4. Additional risk minimisation measures: - None.

Important identified risk: Hyperkalaemia	
Evidence for linking the risk to the medicine	The risk of hyperkalaemia related to depolarizing neuromuscular blockers is well-known and extensively described in the literature.
Risk factors and risk groups	An exaggerated response to suxamethonium, inducing severe hyperkalaemia and resulting in ventricular fibrillation and cardiac arrest, has been reported in: - Patients with pre-existing hyperkalaemia - Patients recovering from major trauma or severe burns - Patients with neurological deficits and acute major muscle wasting or who have been immobilised for prolonged periods of time - Patients with skeletal muscle myopathies (e.g. Duchenne muscular dystrophy)
Risk minimisation measures	Routine risk minimisation measures: - SmPC sections 4.3; 4.4; and 4.8. - Package leaflet sections 2; 4. Additional risk minimisation measures: - None.

Important identified risk: Malignant hyperthermia	
Evidence for linking the risk to the medicine	Although its incidence appears to be extremely low, the risk of malignant hyperthermia related to suxamethonium is well described in the literature.
Risk factors and risk groups	Patients with personal or family history of malignant hyperthermia. Individuals with certain muscle disorders are known to be at higher risk of developing malignant hyperthermia on exposure to such agents secondary to acute rhabdomyolysis with hyperkalaemia
Risk minimisation measures	Routine risk minimisation measures: - SmPC sections 4.3; 4.4; and 4.8. - Package leaflet sections 2; 4. Additional risk minimisation measures: - None.

Important identified risk: Arrhythmia	
Evidence for linking the risk to the medicine	The risk of cardiac dysrhythmia related to suxamethonium is wellknown and described in the literature
Risk factors and risk groups	Suxamethonium may potentiate the bradycardia due to halothane or other agents. Patients taking digitalis-like drugs are more susceptible to develop ventricular arrhythmias.
Risk minimisation measures	Routine risk minimisation measures: - SmPC sections 4.4; 4.5 and 4.8. - Package leaflet sections 2; 4. Additional risk minimisation measures: - None.

Important identified risk: Use in patients with reduced activity or deficiency of plasma cholinesterase	
Evidence for linking the risk to the medicine	Risks related to use of suxamethonium in patients with reduced activity or deficiency of plasma cholinesterase (inherited or related to specific states, pathological conditions or concomitant drug administration) are described in the literature.

Risk factors and risk groups	- Patients known to have an inherited atypical plasma cholinesterase activity. - Some states or pathological conditions (such as chronic debilitating disease, malignancy, chronic anaemia, malnutrition, end-stage hepatic failure, acute or chronic renal failure…) may reduce plasma cholinesterase activity. - Certain drugs (such as organophosphorous, beta agonist sympathomimetics, parasympathetics…) are known to reduce normal plasma cholinesterase activity and may therefore prolong the neuromuscular blocking effects of suxamethonium.
Risk minimisation measures	Routine risk minimisation measures: - SmPC sections 4.3, 4.4 and 4.5. - Package leaflet section 2. Additional risk minimisation measures: - None.

Missing information: Fertility	
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.6 - Package leaflet section 2. Additional risk minimisation measures: - None.

Missing information: Breastfeeding	
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.6 - Package leaflet section 2. Additional risk minimisation measures: - None.

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 Suxamethonium chloride Aguettant.

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

There are no studies required for Suxamethonium chloride Aguettant.