VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Suxamethonium chloride, also known as suxamethonium or succinylcholine, is a medication used to induce muscle relaxation and short-term paralysis, usually to help with tracheal intubation. It is sometimes used in combination with pain medications and sedatives for euthanasia and immobilization of horses. It is colloquially referred to as "sux" in hospital settings.[1]
[1]

Suxamethonium acts as a depolarizing neuromuscular blocker. It acts on nicotinic receptors resulting in persistent depolarization of the motor end plate. It is degraded by butyrylcholinesterase into succinic acid and choline. This hydrolysis by butyrylcholinesterase is much slower than that of acetylcholine by acetylcholinesterase.

It is on the World Health Organization's List of Essential Medicines, a list of the most important medications needed in a basic health system.[2]

VI.2.2 Summary of treatment benefits

Suxamethonium has been tested in various Clinical Trials worldwide to be effective in each of the indications stated above.

VI.2.3 Unknowns relating to treatment benefits

Based on the currently available data, no gaps in knowledge about efficacy in the target population were identified, that would warrant post-authorisation efficacy studies. Furthermore, there is no evidence to suggest that treatment results would be different in any subgroup of the target population, for any of the indications, taking into account factors such as age, sex, race or organ impairment.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Bradycardia	Bradycardia is known to occur and is normally transient but may be prolonged in children.	The SmPC covers such possible events and this will be monitored to ensure the warnings are adequate to prevent such occurrences.
Overdose and muscle paralysis with Respiratory depression	Muscle paralysis and respiratory depression are known to occur in situations involving overdose and careful monitoring and rescue therapy is mentioned in the SmPC	The SmPC covers such possible events and this will be monitored to ensure the warnings are adequate to prevent such occurrences.
Hyperkalaemia-related cardiac arrests	Patients with hyperkalaemia (either from disease states or renal impairment) are more susceptible to cardiac events which may be severe.	The SmPC covers such possible events and this will be monitored to ensure the warnings are adequate to prevent such occurrences.

Important potential risks

Risk	What is known
Suxamethonium administration in patients with a personal or family history of malignant hyperthermia	Suxamethonium can cause severe malignant hyperthermia in patients and rescue therapy is mentioned in the SmPC as a precaution in susceptible patients

Missing information

Risk	What is known
Use in lactation	It is not known to what extent suxamthonium or its metabolites are excreted into breast milk and therefore it is not recommended that patients who have received suxamthonium would breast-feed. However, actual data regarding this is missing.

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

No additional risk minimisation activities are required. Routine pharmacovigilance activities are considered sufficient to monitor the benefit-risk profile of the product and detect any safety concerns.

VI.2.6 Planned post authorisation development plan (if applicable)

There are no studies in the post authorisation development plan.

VI.2.7 Summary of changes to the risk management plan over time

N/A