Part VI: Summary of the risk management plan

Summary of risk management plan for Suxamethonium Chloride 50mg/ml Solution for Injection (suxamethonium chloride) Ampoules

This is a summary of the risk management plan (RMP) for Suxamethonium Chloride 50 mg/ml solution for injection. The RMP details important risks of Suxamethonium Chloride 50 mg/ml solution for injection, how these risks can be minimised, and how more information will be obtained about Suxamethonium Chloride 50 mg/ml solution for injection's risks and uncertainties (missing information).

Suxamethonium Chloride 50 mg/ml solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Suxamethonium Chloride 50 mg/ml solution for injection should be used.

I. The medicine and what it is used for

Suxamethonium Chloride 50 mg/ml solution for injection is authorised for use in anaesthesia as a muscle relaxant to facilitate endotracheal intubation, mechanical ventilation and a wide range of surgical and obstetrics procedures.

It is also used to reduce the intensity of muscular contractions associated with pharmacologically or electrically – induced convulsions. (see SmPC for the full indication). It contains suxamethonium chloride as the active substance and it is given usually by bolus injection.

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

Important risks of Suxamethonium Chloride 50 mg/ml solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Suxamethonium Chloride 50 mg/ml solution for injection'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 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 Suxamethonium Chloride 50 mg/ml solution for injection 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 50 mg/ml solution for injection 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 50 mg/ml solution for injection. 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	None
Important potential risks	None
Missing information	None

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 that are conditions of the marketing authorisation or specific obligation of Suxamethonium Chloride 50 mg/ml Solution for Injection.

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

There are no studies required for Suxamethonium Chloride 50 mg/ml solution for injection.

Summary of risk management plan for Suxamethonium Chloride 50mg/ml Solution for Injection (suxamethonium chloride) Pre-filled Syringes

This is a summary of the risk management plan (RMP) for Suxamethonium Chloride 50 mg/ml solution for injection. The RMP details important risks of Suxamethonium Chloride 50 mg/ml solution for injection, how these risks can be minimised, and how more information will be obtained about Suxamethonium Chloride 50 mg/ml solution for injection's risks and uncertainties (missing information).

Suxamethonium Chloride 50 mg/ml solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Suxamethonium Chloride 50 mg/ml solution for injection should be used.

I. The medicine and what it is used for

Suxamethonium Chloride 50 mg/ml solution for injection is authorised for use in anaesthesia as a muscle relaxant to facilitate endotracheal intubation, mechanical ventilation and a wide range of surgical and obstetrics procedures.

It is also used to reduce the intensity of muscular contractions associated with pharmacologically or electrically – induced convulsions. (see SmPC for the full indication). It contains suxamethonium chloride as the active substance and it is given usually by bolus injection.

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

Important risks of Suxamethonium Chloride 50 mg/ml solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Suxamethonium Chloride 50 mg/ml solution for injection'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 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 Suxamethonium Chloride 50 mg/ml solution for injection 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 50 mg/ml solution for injection 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 50 mg/ml solution for injection. 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	None
Important potential risks	None
Missing information	None

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 that are conditions of the marketing authorisation or specific obligation of Suxamethonium Chloride 50 mg/ml Solution for Injection.

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

There are no studies required for Suxamethonium Chloride 50 mg/ml solution for injection.

Summary of risk management plan for Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning

This is a summary of the risk management plan (RMP) for Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning. The RMP details important risks of Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning, how these risks can be minimised, and how more information will be obtained about Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning's risks and uncertainties (missing information).

Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning should be used.

I. The medicine and what it is used for

Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning is authorised for use in anaesthesia as a muscle relaxant to facilitate endotracheal intubation, mechanical ventilation and a wide range of surgical and obstetrics procedures.

It is also used to reduce the intensity of muscular contractions associated with pharmacologically or electrically – induced convulsions. (see SmPC for the full indication). It contains suxamethonium Chloride as the active substance and it is given usually by bolus injection.

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

Important risks of Suxamethonium Chloride 50 mg/ml solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning'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 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 Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning 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 Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning 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 Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning. 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	None
Important potential risks	None
Missing information	None

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 that are conditions of the marketing authorisation or specific obligation of Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning.

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

There are no studies required for Suxamethonium Chloride Ethypharm 50 mg/ml injektions-/infusionsvæske, opløsning.

Table of contents

Annex 1 – EudraVigilance Interface

Not applicable.

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable.

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable.

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable.

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable.

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable.

Annex 7 - Other supporting data (including referenced material)

Not applicable

Annex 8 – Summary of changes to the risk management plan over time

Version	Approval date / Procedure	Change
1.0	09-Jun-2017	Introduction of new RMP
2.1	N/A	Update of RMP to align with new EMA Guidance on the format of the risk management plan (RMP) in the EU – in integrated format. EMA/164014/2018 Rev.2.0.1 accompanying GVP Module V Rev.2.
2.2		In response to the PVAR dated 03-Oct-2019 the following sections were updated: SV.1 Post-authorisation exposure: SV1.1 Method used to calculate exposure added. SV1.2 Exposure added. SVII.1, SVII.3.1 and SVII.3.2 updated to not applicable. SVII.2 updated. Part II: Module SVIII - Summary of the safety concerns removed as there are none currently. Routine risk minimisation measures, additional risk minimisation measures and summary of risk minimisation measures removed. Summary of risk management plan – Important identified, Potential Risks and Missing information removed.
2.3		In response to the FVAR dated 16-DEC-2019 the section SVII.2 was updated to clarify reasons for risks removal.