Part VI: Summary of the risk management plan

Summary of risk management plan for Corhum solution for cardioplegia

(Sodium chloride, potassium chloride, magnesium chloride hexahydrate, calcium chloride dehydrate, histidine, histidine hydrochloride monohydrate, tryptophan, mannitol, 2-ketoglutaric acid)

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

Corhum solution for cardioplegia's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Corhum solution for cardioplegia should be used.

Important new concerns or changes to the current ones will be included in updates of Corhum solution for cardioplegia's RMP

I. The medicine and what it is used for

Corhum solution for cardioplegia is authorised for cardioplegia during cardiac surgery (see SmPC for the full indication). It contains sodium chloride, potassium chloride, magnesium chloride hexahydrate, calcium chloride dehydrate, histidine, histidine hydrochloride monohydrate, tryptophan, mannitol, 2-ketoglutaric acid as the active substances and it is a solution for perfusion.

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

Important risks of Corhum solution for cardioplegia, together with measures to minimise such risks and the proposed studies for learning more about Corhum solution for cardioplegia'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 Corhum solution for cardioplegia is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Corhum solution for cardioplegia 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 Corhum solution for cardioplegia. 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	Electrolyte disturbances due to inflow of large volumes into the systemic circulation

Important potential risks	None
Missing information	None

II.B Summary of important risks

Important Identified Risk(s)	**Electrolyte disturbances due to inflow of large volumes into the systemic circulation**
Evidence source(s) and strenght of evidence	The HTK solution is intended for perfusion and flushing donor kidneys prior to removal from the donor and for preserving the kidney during hypothermic storage and transport to the recipient. The composition of HTK solution is similar to that of extracellular fluid. All of the components of the HTK solution occur naturally in the body. The HTK solution is relatively low in potassium concentration so that residual solution in the transplanted organ poses no danger to the recipient. This is particularly important in organs that take up relatively large amounts of the perfusate, which may find its way into the recipient's circulation. Custodiol HTK solution is indicated for perfusion and flushing donor kidneys prior to removal from the donor or immediately after removal from the donor. Ths solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.
Risk factors and risk groups	Not applicable
Risk minimisation measures	*Routine risk minimization measures:* No routine pharmacovigilance activities beyond adverse reactions reporting and signal detection (e.g. specific adverse reaction follow-up questionnaire) are proposed. *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 Corhum solution for cardioplegia

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

There are no studies required for Corhum solution for cardioplegia