

Part VI: Summary of the risk management plan

Summary of risk management plan for Lactated Ringer's solution for infusion (Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Sodium Lactate)

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

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

Important new concerns or changes to the current ones will be included in updates of Lactated Ringer's solution for infusion's RMP.

I. The medicine and what it is used for

Lactated Ringer's solution for infusion is authorised for the following indications:

- Restoration of extracellular fluid and electrolytes balances or replacement of extracellular fluid loss where isotonic concentrations of electrolytes are sufficient.
- Short-term volume replacement (alone or associated with colloid) in case of hypovolaemia or hypotension.
- Regulation or maintenance of metabolic acidosis balance and/or treatment of mild to moderate metabolic acidosis (except lactic acidosis) (see SmPC for the full indication).

It contains sodium chloride, potassium chloride, calcium chloride dihydrate and sodium lactate as active substances and it is given intravenously.

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

Important risks of Lactated Ringer's solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Lactated Ringer's solution for infusion'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.

Confidential Information

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*.

II.A List of important risks and missing information

Important risks of Lactated Ringer's solution for infusion 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 Lactated Ringer's solution for infusion. 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

Not applicable.

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 Lactated Ringer's solution for infusion.

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

There are no studies required for Lactated Ringer's solution for infusion.