PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Plasma-Lyte 148 (pH 7.4)

This is a summary of the Risk Management Plan (RMP) for Plasma-Lyte 148 (pH 7.4) solution for infusion (hereafter referenced as Plasma-Lyte 148 (pH 7.4)). The RMP provides details on the risks of Plasma-Lyte 148 (pH 7.4).

The Summary of Product Characteristics (SmPC) and Package Leaflet (PL) for Plasma-Lyte 148 (pH 7.4) provide essential information to healthcare professionals and patients on how Plasma-Lyte 148 (pH 7.4) should be used.

New safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Plasma-Lyte 148 (pH 7.4) is authorized for fluid replacement (e.g., after burns, head injury, fracture, infection, and peritoneal irritation), as intraoperative fluid replacement, in hemorrhagic shock and clinical conditions requiring rapid blood transfusions (compatibility with blood), in mild to moderate metabolic acidosis, also in case of lactate metabolism impairment. It contains sodium chloride, potassium chloride, magnesium chloride hexahydrate, sodium acetate trihydrate, and sodium gluconate as the active substances, and it is given intravenously.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

There are no risks included in the RMP for Plasma-Lyte 148 (pH 7.4); however, measures to minimize the risks for any medicinal products may be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size – the amount of medicine in a pack is chosen so as 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).

Together, these measures constitute *routine risk minimization measures*.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 medicinal products are risks that need special risk management activities to further investigate or minimize 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 medicinal products. Potential risks are concerns for which an association with the use of the medicinal product is possible based on available data, but this association has not been established yet and needs to be further monitored. Missing information refers to information on the safety of the medicinal product that is currently missing and further information may need to be collected (e.g., on the long-term use of the medicine).

There are no safety concerns for Plasma-Lyte 148 (pH 7.4).

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks and missing information

There are no safety concerns included in this RMP. All risks associated with the use of Plasma-Lyte 148 (pH 7.4) are considered fully characterized and appropriately managed with routine risk minimization measures in the product information which are fully integrated into standard clinical practice.

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligations of Plasma-Lyte 148 (pH 7.4).

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

There are no studies required for Plasma-Lyte 148 (pH 7.4).