VI.2 Elements for a Public Summary

VI.2.1 Overview of Disease Epidemiology

Around the world, fluid replacement therapy may be used for seriously ill patients or patients receiving surgery. Globally, such therapy may be used to effectively restore blood volume and provide an adequate supply of oxygen and nutrients to the tissue following various traumas including burns, head injury, broken bones, infection, abdominal irritation, and surgery. Among the various traumas, burn injuries represent a common injury worldwide that can require hospitalization for 4% to 22% of victims who often suffer severe fluid loss. Other injuries that could require fluid therapy such as head injury occur at a frequency of 200 to 300 cases per 100 000 population. Additionally, fractures, which occur with a frequency of 9 to 23 cases per 1 000 population, can require

fluid therapy due to significant blood loss and fluid imbalance. During surgery, fluid replacement also frequently serves as a necessary surgical practice to maintain blood volume and prevent fluid loss complications. Traditionally, fluid replacement therapy is used to manage many serious conditions by supplying oxygen and critical nutrients to vital organs, which may also prevent further injury. Overall, the clinical management and resulting clinical outcome differs in patients receiving fluid therapy, depending on the underlying trauma or condition.

VI.2.2 Summary of Treatment Benefits

Plasma-Lyte may be used to replace fluids in the body after injury, such as a burn, head injury, fracture, or infection; during surgery; or when certain medical conditions (such as shock) require immediate blood transfusions.

Plasma-Lyte without Dextrose solutions are similar to plasma (a component of the blood). The advantages of Plasma-Lyte without Dextrose include fluid replacement, correcting the amount of various minerals (called electrolytes) in the body, and helping to balance the body's pH. Because Plasma-Lyte contains electrolytes in amounts that are similar to those already contained in the body, it does not disturb the pH balance of the body the way other replacement fluids might.

VI.2.3 Unknowns Relating to Treatment Benefits

The safety and effectiveness of Plasma-Lyte in children have not been established. Additionally, there are no adequate data from the use of Plasma-Lyte in pregnant or lactating women. The potential risks and benefits for each patient should be carefully considered before using Plasma-Lyte.

VI.2.4 Summary of Safety Concerns

Table 17. Important Identified Risks

Risk	What is Known	Preventability
Allergic reactions (Hypersensitivity reactions)	Allergic reactions can range from mild skin reactions to life-threatening reactions across the entire body which may be fatal. Patients with a history of allergic reactions to Plasma-Lyte without Dextrose or any of the components in the product are most at risk.	Plasma-Lyte must not be used in patients with who have ever experienced an allergic reaction to Plasma-Lyte or any of its ingredients.

Table 18. Important Potential Risks

Risk	What is Known (Including Reason Why it is Considered a Potential Risk)
Imbalance of minerals especially in patients with metabolism, heart, and kidney problems (Electrolyte disorders especially in patients with underlying metabolic disorders, cardiac and renal impairment)	As Plasma-Lyte without Dextrose contains minerals, imbalances in the body's minerals and related medical conditions may occur if Plasma-Lyte without Dextrose therapy is not carefully monitored. Patients with a history of metabolic, heart, and kidney problems are most at risk.
Over-hydration especially in patients with heart and kidney problems (Fluid overload conditions especially in patients with underlying cardiac and renal impairment)	An overload of fluids in the body may occur after of over-hydration and/or receiving too much fluid and can, for example, lead to fluid in the lungs or swelling in the lungs. Patients with a history of heart and kidney problems are most at risk. Patients should be monitored for over-hydration. Careful monitoring of the patient's fluid and mineral balance and an accurate record of the patient's fluid taken into the body (for example by drinking or intravenous fluids) and fluids leaving the body (for example, by body fluids) should be kept. Solutions containing sodium or salt should be used with great care, if at all, in patients with heart failure, severe kidney disorders, and in medical conditions in which there is salt retention with swelling.

Table 19. Missing Information

Risk	What is Known
There is little data from clinical trials on use in children (Insufficient clinical data on paediatric patients)	While the safety and effectiveness of Plasma-Lyte without Dextrose have not been established in children in clinical studies there is information on use in children from use in hospitals which is supported by scientific literature.
There is little data on use in pregnant and breastfeeding women (Insufficient data on pregnant and lactating women)	While the safety and effectiveness of Plasma-Lyte without Dextrose have not been established in pregnant and breastfeeding women, the risks and benefits should be considered carefully in pregnant and breastfeeding women.

VI.2.5 Summary of Risk Minimization Measures by Safety Concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists, and other healthcare professionals with details on how to use the medicine, the risks, and recommendations for minimizing 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 minimization measures.

The Summary of Product Characteristics and the Package Leaflet for Plasma-Lyte without Dextrose will be located in the Plasma-Lyte without Dextrose's EPAR page.

VI.2.6. Planned Post-Authorization Development Plan

There are currently no ongoing or planned post-authorization safety studies for Plasma-Lyte without Dextrose.

Studies which are a Condition of the Marketing Authorization

There are no studies which are conditions of the marketing authorization.

VI.2.7 Summary of Changes to the Risk Management Plan Over Time

Major Changes to the Risk Management Plan Over Time

This is the first EU RMP for Plasma-Lyte without Dextrose.