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 intravascular volume and provide an adequate supply of oxygen and nutrients to the tissue following various injuries including burns, head injury, infection, and surgery. Among the 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. Infections are also a common problem for patients in intensive care units (ICUs), which can lead to systemic blood infections (sepsis) and increased death rates (mortality), especially in children and the elderly. Worldwide, sepsis occurs in 6% to 30% of all ICU patients with infections.

Fluid replacement frequently serves as a necessary 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.

VI.2.2 Summary of Treatment Benefits

PLASMA-LYTE 148 & GLUCOSE 5% may be used to replace fluids in the body after injury or during surgery, or to treat certain medical conditions that affect the body's metabolism/pH. This product can be used in these types of patients in order to provide a source of water, electrolytes and energy to restore the body's normal fluid and mineral (electrolyte) balance.

VI.2.3 Unknowns Relating to Treatment Benefits

The safety and effectiveness of PLASMA-LYTE 148 & GLUCOSE 5% have not been evaluated in clinical studies in pediatric patients or pregnant and/or lactating females.

VI.2.4 Summary of Safety Concerns

Table 16. Important Identified Risks

Risk	What is Known	Preventability
Blood sugar problem (too low or too high blood sugar levels) in children/newborns (Glucose abnormalities (hypo- or hyperglycemia) in	Newborns, especially those born premature and with low birth weight who have problems regulating their own blood sugar levels, are at increased risk of developing too low or too high blood sugar levels (hypo-	The rate the drug is administered depends on the age, weight and medical condition of the patient. This rate should be determined by a physician experienced in IV

Table 16. Important Identified Risks

Risk	What is Known	Preventability
pediatrics/newborns)	or hyperglycemia) when treated with IV fluids that contain sugar.	fluid therapy for children/newborns.

Table 17. Important Potential Risks

Risk	What is Known
Nervous system complications in patients with stroke or head injury, caused by high blood sugar levels (Hyperglycemia-induced worsening of neurological status in patients with cerebrovascular events and/or head trauma)	Patients who are treated with IV solutions that contain sugar may develop blood sugar levels that are higher than normal. A high blood sugar level (hyperglycemia) has been known to worsen nervous system complications in patients with stroke or head injury.

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 the SmPC in lay language is provided in the form of the package leaflet. The warnings and precautions in these documents are known as routine risk minimization measures. For PLASMA-LYTE 148 & GLUCOSE 5%, these routine risk minimization measures are considered sufficient.

VI.2.6 Planned Post-authorization Development Plan

There are currently no planned post-authorization development studies for PLASMA-LYTE 148 & GLUCOSE 5%.

Studies which are a Condition of the Marketing Authorization

Not applicable.

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

This is the first RMP in the EU for PLASMA-LYTE 148 & GLUCOSE 5%.

Table 18. Major Changes to the Risk Management Plan Over Time

Version	Date	Safety Concern	Comment
1	22 JUN 2017	Glucose abnormalities (hypo- or hyperglycemia) in	Included as an important identified risk in the first version of the

Table 18. Major Changes to the Risk Management Plan Over Time

Version	Date	Safety Concern	Comment
		pediatrics/newborns	PLASMA-LYTE 148 & GLUCOSE 5% EU RMP.
		Hyperglycemia-induced worsening of neurological status in patients with cerebrovascular events and/or head trauma	Included as an important potential risk in the first version of the PLASMA-LYTE 148 & GLUCOSE 5% EU RMP.