VI.2 ELEMENTS FOR A PUBLIC SUMMARY

VI.2.1 OVERVIEW OF DISEASE EPIDEMIOLOGY

Benelyte (previously Elo-Infant) is indicated for pediatric patients such as neonates (0 to ≤28 days), infants (28 days to ≤3 months), toddlers (3 months to ≤2 years), children (2 to ≤12 years), and adolescents (12 to ≤14 years) as follows:

– Perioperative plasma-isotonic fluid and electrolyte replacement with partial coverage of carbohydrate requirements,

– Short-term intravasal volume replacement,

– Treatment of isotonic dehydration,

– Use as carrier solution for compatible electrolyte concentrates and medicinal products.

Due to the inconsistency in the population treated (children of different age groups), the indications (treatment of hypovolemia under several clinical conditions and the use as a carrier solution), and different underlying diseases no data on disease epidemiology are available.

VI.2.2 SUMMARY OF TREATMENT BENEFITS

Benelyte (previously Elo-Infant) is an electrolyte solution for pediatric patients that has been adjusted in its most important cation composition to the respective plasma concentration and is used for the correction of fluid and electrolyte disturbances. The solution has been adapted in its composition to the typcial metabolic changes occurring in children during surgery and anesthesia. The supply of electrolytes restores or maintains normal osmotic conditions in the extra- and intracellular compartments. In addition, the solution also contains 10 mg/ml carbohydrates as glucose.

Acetate is oxidised and has an alkalescent effect. Administration of Benelyte (previously Elo-Infant) initially leads to replenishment of the interstitial space that accounts for approximately two-thirds of the extracellular compartment. Approximately one-third of the supplied volume remains in the intravascular space only. Therefore, the solution only has a short-term hemodynamic effect.

VI.2.3 UNKNOWNS RELATING TO TREATMENT BENEFITS

Not applicable

VI.2.4 SUMMARY OF SAFETY CONCERNS

Safety Concern	What is known	Preventability
Important Identified Risks		
Allergic reactions (hypersensitivity reactions)	Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 of the SmPC may occur	Limited, Benelyte (previously Elo-Infant) is contraindicated in patients with hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 of the SmPC
Hyperhydration	Administration of fluid may further deteriorate the clinical condition of patients with pre-existing hyperhydration.	Yes, Benelyte (previously Elo-Infant) is contraindicated in patients with status of hyperhydration
Hyperglycemia	Benelyte (previously Elo-Infant) may deteriorate conditions of hyperglycemia	Yes, similar electrolyte-similar electrolyte-containing solutions for infusion without glucose and/or acetate should be used, if possible. In addition, in this patient group closer monitoring, particularly, blood glucose level and acid-base balance as well as electrolyte balance is required in order to detect resulting risks at an early stage
Incompatibilities with other medicinal products	Incompatibility of the medicinal product to be added to Benelyte (previously Elo-Infant) must be assessed before addition. In general, it can be stated that the following medicinal products (groups) must not be mixed with Benelyte (previously Elo-Infant): Medicinal products that might form hardly soluble precipitations with the constituents of the solution. (The preparation contains Ca2+ ions. Precipitation may occur with the addition of inorganic phosphate, hydrogen carbonate/ carbonate or oxalate.), Medicinal products that are not stable in an acid pH-range or do not exhibit	Yes, Benelyte (previously Elo-Infant) must not be mixed with substances described under 6.2 of the SmPC.

Safety Concern	What is known	Preventability
	optimum efficacy or decompose, Solutions for infusion that contain glucose must not be administered simultaneously through the same infusion equipment with blood because of the possibility of pseudo-agglutination.	
Liver steatosis	Excessive supply of glucose, in particular, in the course of a post-aggression syndrome, can considerably increase the disturbance of glucose utilisation and contribute to enhanced conversion of glucose to fat resulting from impaired oxidative glucose utilisation. This in turn may be associated with an increased carbon dioxide burden of the organism (problems with weaning from respirator) and additional fat infiltration in the tissues, specifically in the liver.	Yes, controls of blood glucose levels are required postoperatively, post-traumatically and in other disorders of glucose tolerance (hyperglycemia).
Metabolic alkalosis	Benelyte (previously Elo-Infant) may deteriorate conditions of metabolic alkalosis	Yes, similar electrolyte-similar electrolyte-containing solutions for infusion without glucose and/or acetate should be used, if possible. In addition, in this patient group closer monitoring, particularly, blood glucose level and acid-base balance as well as electrolyte balance is required in order to detect resulting risks at an early stage
Lactic acidosis and other metabolic acidoses	By glycolysis, glucose is metabolised to pyruvate or lactate. Lactate can be partially re-introduced into the glucose metabolism (CORI cycle). Under aerobic conditions pyruvate is completely oxidised to carbon dioxide and water. The final products of this complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water). A precondition for optimal utilisation of supplied glucose is a normal electrolyte and acid-base status. Particularly, acidosis can be a sign of impaired oxidative metabolism.	Yes, caution is required specifically in neonates, infants, and toddlers because the risk of developing lactic acidosis cannot be ruled out when using acetate as contained in this medicinal product in very rare disorders of acetate metabolism. These very rare disorders of acetate metabolism may appear for the first time when administering this medicinal product.

Safety Concern	What is known	Preventability
		Benelyte (previously Elo-Infant) should be used in pediatric patients with congenital disturbance of lactate utilisation after a careful risk-benefit-balance only.
Disturbances in potassium metabolism (especially hyperkalemia)	There is a strong correlation between electrolyte and carbohydrate metabolism which particularly affects potassium. Utilisation of glucose is associated with increased potassium requirements. If this relationship is not taken into account considerable disturbances of potassium metabolism may occur which can lead to massive cardiac arrhythmias amongst other conditions.	Yes, monitoring of electrolyte and fluid status as well as the acid-base balance is necessary.
Hyperchloremia	Benelyte (previously Elo-Infant) may deteriorate conditions of hyperchloremia.	Yes, monitoring of electrolyte and fluid status as well as the acid-base balance is necessary.
Hypernatremia	Benelyte (previously Elo-Infant) may deteriorate conditions of hypernatremia.	Yes, monitoring of electrolyte and fluid status as well as the acid-base balance is necessary.

Important potential risks

None identified

Missing information

Risk	What is known
Data on fertile, pregnant or breast-feeding women	There are no or limited amount of data from the use of Benelyte (previously Elo-Infant) in fertile, pregnant and breastfeeding women. Although no data are available, negative effects are unlikely to occur with the intended use of Benelyte (previously Elo-Infant) when electrolyte, fluid and acid/base levels are carefully monitored.

VI.2.5 SUMMARY OF RISK MINIMISATION MEASURES BY SAFETY CONCERN

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

The Summary of Product Characteristics for Benelyte (previously Elo-Infant) can be found in Annex 2 of this RMP.

This medicine has no additional risk minimisation measures.

VI.2.6 PLANNED POST-AUTHORISATION DEVELOPMENT PLAN

Not applicable.

VI.2.7 SUMMARY OF CHANGES TO THE RISK MANAGEMENT PLAN OVER TIME

Not applicable.