Part VI: Summary of the risk management plan by product

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology (Maximum 150 words per indication)

Parenteral nutrition is indicated in infants and children who are unable to sustain their nutritional requirements by oral or enteral intake, such as children who suffer from chronic malnutrition or who are at high risk for developing malnutrition as a result of acute medical illness (digestive diseases are the most represented) or prolonged post-operative recovery. The maximum period of tolerable undernutrition depends on the patient's age, baseline nutrition status, and underlying medical conditions. Parenteral nutrition may concern patients who may require nutritional support for a few weeks during hospitalisation, to patients relying on long-term home parenteral nutrition. Parenteral nutrition is supplemented with trace elements, i.e. elements that occur in very small amounts as constituents of the human organism, and are necessary for its growth, development, and health.

VI.2.2 Summary of treatment benefits

Trace elements solutions for IV administration are well-known products that have been used for medical purposes for decades, and numerous guidelines have been published over the years, with recommendations on the standard trace elements ranges to provide for parenteral nutrition. NUTRYELT PAEDIATRIC contributes to the organism needs in zinc, copper, manganese, iodine and selenium. As the composition of NUTRYELT PAEDIATRIC was defined on the basis of the most recent guidelines and recommendations on paediatric parenteral trace elements requirements, and as all the trace elements contained in NUTRYELT PAEDIATRIC have been used for parenteral nutrition for many decades, no clinical studies were performed specifically with NUTRYELT PAEDIATRIC.

VI.2.3 Unknowns relating to treatment benefits (1 short paragraph per indication of 50 words maximum)

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Copper and/or Manganese toxicity related administration of NUTRYELT in patients with disturbances in bile flow (Copper and/or Manganese toxicity related to administration in patients with pronounced cholestasis)	Copper and Manganese are eliminated predominantly through the bile. Disturbance in bile flow would lead to an accumulation of copper and manganese and a risk of toxicity.	Patient Information Leaflet: Blood levels of trace elements will be monitored regularly by your doctor during the treatment, and your doctor will adapt the dosage of NUTRYELT® PAEDIATRIC accordingly
Copper toxicity related to administration of NUTRYELT in patients with an excess of copper in their body (Copper toxicity related to administration in patients with Wilson's	Administration of NUTRYELT in patients with an excess of copper in their body would lead to an accumulation of copper and a risk of toxicity.	Patient Information Leaflet: **Your child should not receive NUTRYELT® PAEDIATRIC:** – if he/she suffers from Wilson's disease (an inherited disorder where there is excessive amount of copper in the body).

Risk	What is known	Preventability
disease)		
Allergy (Hypersensitivity)	Cases of hypersensitivity reactions including fatal anaphylactic reactions have been reported in patients receiving IV iron-containing products	Patient Information Leaflet: **Your child should not receive NUTRYELT® PAEDIATRIC:** – if he/she is allergic (hypersensitive) to any of the ingredients of NUTRYELT® PEDIATRIC (See section 6 of this leaflet).

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.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None.

VI.2.7 Summary of changes to the Risk Management Plan over time

Major changes to the Risk Management Plan over time: not applicable.