RISK MANAGEMENT PLAN

Active substance(s) (INN or common name):	Zinc gluconate, Copper gluconate, Manganese gluconate, Sodium fluoride, Potassium iodide, Sodium selenite, Sodium molybdate, Chromium chloride, Ferrous gluconate.
Pharmaco-therapeutic group (ATC Code):	B05XA31
Name of Marketing Authorisation Holder or Applicant:	Laboratoire Aguettant
Number of medicinal products to which this RMP refers:	1. 10-ml polyropylene ampoule NUTRYELT
Product(s) concerned (brand name(s)):	NUTRYELT

Data lock point for this RMP	26-Apr-2013	Version number	1.0
Date of final sign off	26-Jun-2014		

Part VI: Summary of activities in 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 may be indicated for a very large numbers of conditions and diseases, such as cancer and severe gastrointestinal disorders. 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.

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. As the composition of NUTRYELT was defined on the basis of the most recent guidelines on adult parenteral nutrition, and as all the trace elements contained in NUTRYELT have been used for parenteral nutrition for many decades, no clinical studies were performed specifically with NUTRYELT.

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: Do not use if you have a pronounced cholestasis (yellowing of the skin or whites of the eyes caused by liver or blood problem).
Iron toxicity related to administration of NUTRYELT in patients with iron overload (Iron toxicity related to administration in patients with hemochromatosis)	Administration of NUTRYELT in patient with iron overload would lead to an accumulation of iron and a risk of toxicity.	Patient Information Leaflet: Do not use if you have an excess of iron in the body (hemochromatosis).
Copper toxicity related to administration of NUTRYELT in patients with an excess of copper in their body (Copper toxicity related to administration	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: Do not use if you have an excess of copper in the body (Wilson´s disease).

Risk	What is known	Preventability
in patients with Wilson's disease)		
Allergy (Hypersensitivity)	Cases of hypersensitivity reactions including fatal anaphylactic reactions have been reported in patients receiving IV iron-containing products	Patient Information Leaflet: Do not use if you are allergic (hypersensitive) to any of the ingredients of NUTRYELT.

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.