VI.2 ELEMENTS FOR A PUBLIC SUMMARY

VI.2.1 OVERVIEW OF DISEASE EPIDEMIOLOGY

Malnourish people like cancer patients need extra nutrition. If an oral or enteral feeding is not possible, there is no alternative to parenteral nutrition.

VI.2.2 SUMMARY OF TREATMENT BENEFITS

SmofKabiven content of amino acid, lipid emulsion, glucose and electrolytes consists of a three chamber bag system. Glucose in varying concentrations is well established as the optimal carbohydrate source for PN. Aminoven 10% has been authorized for marketing since January 1999 and SMOFlipid 20% has been authorized since February 2004 in several countries worldwide. All substance are well known for parenteral nutrition and the different packages sizes are intended for patients with high, moderately increased or basal nutrition requirements.

VI.2.3 UNKNOWNS RELATING TO TREATMENT BENEFITS

SmofKabiven is a well-established product. There are no significant unknowns regarding the benefits of the product.

SmofKabiven content of amino acid, lipid emulsion, glucose and electolytes to meet the requirements for parenteral nutrition. The main rationale behind the product is that it should be suitable for the majority of patients requiring intravenous nutrition (IVN). This is a complex task, since inevitably this needs to be a compromise of a range of different requirements- the basal needs of some home IVN patients, the variably increased needs of some home IVN patients if they have large losses from the small bowel, the increased needs of patients post-surgery if they are hypermetabolic or have increased losses, or the increased needs of the patient recovering from a severely depleted state. It was, and still is recognised, that some patients have increased, and some decreased requirements, relative to the composition in SmofKabiven.

VI.2.4 SUMMARY OF SAFETY CONCERNS SMOFKABIVEN

Safety Concern	What is known	Preventability
Important Identified Risks		
Metabolic/electrolytes abnormalities	Patients with renal disorders are at risk of alternating blood volume and changes in blood electolytes.	In kidney disease individual adjustment of doses as well as regular clinical and laboratory controls are required.
	Metabolic conversions of amino acids are complex and inborn errors of amino acids can thus impair or hinder their physiologic metabolism. Serious adverse drug effects can result from accumulations of metabolites.	In altered amino acids individual adjustment of doses as well as regular clinical and laboratory controls are required.
	Excessive intake of potassium may cause hyperkalaemia which may cause nerve and muscle disorders. As the heart is a muscle irregular heart rate and also heart arrest may occur. Hypermagnesaemia is an abnormally elevated level of magnesium in the blood which may cause impaired breathing, impaired heart function and impaired function of the nerves which resulted in dizziness, sleepiness and decreased tendon reflexes.	SmofKabiven should not be administered when serum levels of any of the included electrolytes are pathologically elevated as for any PN.
	SmofKabiven is contraindicated in patient with severe post-traumatic conditions, severe and not corrected diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis, and severe sepsis.	Serum glucose, electrolytes and osmolarity as well as fluid balance, acid-base status and liver enzyme tests should be monitored.
	Attention should be given in patients with impaired lipid metabolism, which	Serum glucose, electrolytes and osmolarity as well as fluid

Safety Concern	What is known	Preventability
	may occur in patients with renal failure, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism and sepsis.	balance, acid-base status and liver enzyme tests should be monitored.
	Impaired capacity to eliminate triglycerides can lead to “Fat overload syndrome” which may be caused by overdose This is characterised by hyperlipemia, fever, fat infiltration, a great liver with or without jaundice, greater spleen, anemia, leukopenia, thrombocytopenia, coagulation disorder etc. The symptoms are usually reversible if the infusion of the lipid emulsion is discontinued.	If symptoms of overdose of fat or amino acids occur, the infusion should be slowed down or discontinued.
	If the glucose clearance capacity of the patient is exceeded, hyperglycaemia will develop..	If hyperglycaemia occurs, it should be treated according to the clinical situation either by appropriate insulin administration and/or adjustment of the infusion rate .
Important Potential Risks		
Refeeding syndrome	In underfed patients, initiation of PN can induce refeeding syndrome. This is a series of metabolic and biochemical changes that occur as a consequence of reintroduction of feeding after a period of starvation or fasting. Therefore, the applicant adequately warns that fluid shifts can result influid into the lungs, heart failure, irregular heart rate , and decrease in serum concentration of potassium, phosphate, magnesium, and water-soluble vitamins	Careful initiation of slow infusion and controls with appropriate adjustments are recommended
Missing Information		
Posology for children	SmofKabiven is not recommended for use in children as there is no clinical experience	Not applicable.

Safety Concern	What is known	Preventability
Use in pregnant and lactating women	No specific studies have been performed to assess the safety of SmofKabiven during pregnancy.	SmofKabiven should only be given to pregnant and breast-feeding women after careful consideration.

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 and the Package leaflet for SmofKabiven 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.