VI.2 Elements for a Public Summary

VI.2.1 Overview of Disease Epidemiology

Some patients who are in the hospital or who require home treatment may not have a proper nutritional status. This may occur because a person is unable to eat, because of illness leading them to need more nutrients than normal, or due to both of these reasons. When someone does not have enough nutrients in the body, they suffer with a condition called malnutrition.

The number of patients in the hospital who are at risk of malnutrition ranges from 9% to 55%. Some conditions that put patients at risk for malnourishment include cancer, infections, neurologic disorders or other illnesses (e.g., HIV/AIDS). Those suffering from malnutrition may have an increased risk of a prolonged hospitalization, other medical complications, and/or death. Therefore, patients who are malnourished may benefit by receiving this nutrition intravenously (through a vein).

VI.2.2 Summary of Treatment Benefits

If a person is not able to eat, sometimes the only way to get nutrients may be from a medicine that goes into the vein. Such medicine is called parenteral nutrition (PN) and has been around for over 30 years. PN contains different nutrients called amino acids (protein), lipids (fat), glucose (sugar for carbohydrates), electrolytes (minerals), vitamins, and trace elements. The different nutrients in PN can be given to the patient separately or they can be mixed together and given to the patient at the same time.

Finomel Peri/Finomel is Baxter's proposed PN therapy that is presented in a multi-chamber bag. The nutrients are separated into 3 chambers (one for amino acids and electrolytes, one for glucose and one for lipids). Having all the nutrients in one bag is helpful for many practical reasons. It may also decrease some of the risks associated with PN (such as infection and medication errors). Additionally, vitamins and trace elements can be added to the bag if the patient needs them for nutritional support.

There are two formulations of this PN therapy including Finomel, which is designed to be infused into a central vein, and Finomel Peri which is designed to be infused into a peripheral or central vein. Both formulations are designed to deliver nutrition to patients when eating or use of a feeding tube is not possible.

VI.2.3 Unknowns Relating to Treatment Benefits

The components in Finomel Peri/Finomel are comparable to other well-established PN products that have been marketed for more than 10 years. Literature establishing the

safety and efficacy of the components of Finomel Peri/Finomel is available in the public domain. The safety and effectiveness of Finomel Peri/Finomel have not been evaluated in clinical studies in pediatric patients or pregnant and/or lactating females.

VI.2.4 Summary of Safety Concerns

There are no safety concerns associated with Finomel Peri/Finomel included in this RMP.

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 this in lay language is provided in the form of the package leaflet. The measures in these documents are known as routine risk minimization measures.

This medicine has no additional risk minimization measures.

VI.2.6 Planned Post-authorization Development Plan

There are currently no planned post-authorization development studies for Finomel Peri/Finomel.

Studies which are a Condition of the Marketing Authorization

Not applicable.

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

Table 1. Major Changes to the Risk Management Plan Over Time

Version	Date	Safety Concerns	Comment
1.0	11 AUG 2017	Pulmonary embolism due to pulmonary vascular precipitates	Included as important potential risks in the first version of the Finomel Peri/Finomel RMP
		Fat overload syndrome	
		Refeeding syndrome	
		Thromboembolic events due to ceftriaxone-calcium salt precipitation	
		Parenteral nutrition-associated liver disease (PNALD)	
1.1	07 MAY 2018	All safety concerns deleted per assessor request.	All safety concerns associated with the use of Finomel Peri/Finomel are considered fully characterized and appropriately managed with routine risk

Table 1. Major Changes to the Risk Management Plan Over Time

Version	Date	Safety Concerns	Comment
			minimization measures in the product information which are fully integrated into standard clinical practice.