VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Vitamin deficiency may develop into a specific deficiency syndrome with serious clinical conditions. All populations, regardless of age, sex, race, or geographic region may be affected and patients requiring parenteral nutrition (PN), especially long term PN have an increased risk.

Because the presence of vitamin deficiency syndrome develops over time, a hospitalized patient who is receiving total parenteral nutrition (TPN) for not longer than a week is very unlikely to develop deficiency due to inadequate intake without a preexisting deficiency. In general vitamin deficiency syndrome has been reported in patients receiving parenteral nutrition (PN) for long periods. Notwithstanding, the physicians should not wait for the onset of the symptoms and therefore vitamin supplements should be provided together with fluids, glucose, amino acids, lipids, minerals and trace elements right from the beginning of PN.

Patients may need PN for a variety of diseases or conditions that impair food intake, nutrient digestion or absorption. The main risk groups are severely ill, geriatric or cancer patients and patients with gastrointestinal diseases like inflammatory bowel diseases, intestinal failure or short bowel syndrome.

No centralized data regarding the number of patients receiving PN are available; data varies across different countries, or even within the same country, and is dependent on multiple factors.

VI.2.2 Summary of treatment benefits

Viant is a multivitamin preparation, containing all 13 vitamins; and is indicated for adults and children aged 11 years and above, to maintain the daily requirements, if oral administration is contraindicated, impossible or insufficient and a vitamin substitution is necessary in the setting of PN.

The constituents of Viant are generally established for medicinal use, being both efficient and safe.

The primary objective of PN is to maintain or improve the nutritional status of patients who, for a critical period of time are unable to eat adequately. Vitamins are essential for a normal body function. Because of different conditions that prevent the patient to take the necessary amount of vitamins from food, the physician should not await the development of clinical signs of deficiency and should administer parenteral vitamins as an integral part of PN. One vial per day complies with the current recommendations for the normal daily vitamin requirements; if there are specific deficiencies of individual vitamins, extra supplementation of these vitamins is required.

Some patients need PN only temporarily. This may be the case in patients with inflammatory bowel diseases, cancer or recovering from surgery, injuries, or burns. But for patients with severe gastrointestinal failure and SBS, PN was proven to be mandatory for long-term survival, to sustain and maintain quality of life, and to promote rehabilitation.

VI.2.3 Unknowns relating to treatment benefits

There are no unknowns related to treatment benefits for Viant powder for solution for infusion.

VI.2.4 Summary of safety concerns

Important identified risks

None

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
< Influence on coagulation adjustment in patients on anticoagulant therapy with coumarin derivates (anticoagulant therapy)>	Patients receiving anticoagulant therapy have an increased risk of bleeding, with life-threatening complications, especially cerebral hemorrhage. Vitamin K administration can rapidly reverse the effect of anticoagulant drugs; but on the other hand vitamin A or E can increase the effect of anticoagulant drugs. For patients on PN who are also on coumarin anticoagulants it is indicated to periodically measure the prothrombin time to ensure that the patient is

Risk	What is known (Including reason why it is considered a potential risk)
	receiving the appropriate dose of vitamins A, E, K and anticoagulant drug. The vitamin E doses provided by Viant are too low to aggravate coagulation disturbances even in patients with deficiency of vitamin K or patients maintained on anticoagulants. Also vitamin K is substituted concomitantly with Viant.

Missing information

None

VI.2.5 Summary of risk minimisation measures by safety concern

Not applicable. No additional risk minimization measures are planned.

VI.2.6 Planned post authorisation development plan

Not applicable. There is no post authorisation development plan in place.

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

Not applicable, as this is the first RMP for the product.