PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Numeta

This is a summary of the Risk Management Plan (RMP) for Numeta. The RMP provides details on the important risks of Numeta, how these risks can be minimized, and how more information will be obtained about the important risks for Numeta.

The Summary of Product Characteristics (SmPC) and Package Leaflet (PL) for Numeta provide essential information to healthcare professionals and patients on how Numeta should be used.

New safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Numeta is authorized for parenteral nutrition in pediatric patients when oral or enteral nutrition is not possible, insufficient, or contraindicated; refer to the SmPC for complete indication wording. It contains glucose, amino acids with electrolytes, and lipids as the active substances, and it is given intravenously.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

There are no important risks included in the RMP for Numeta; however, measures to minimize the risks for any medicinal products may be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size – the amount of medicine in a pack is chosen so as to ensure that the medicine is used correctly;
- The medicine's legal status – the way a medicine is supplied to the patient (e.g., with or without prescription).

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of medicinal products are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of medicinal products. Potential risks are concerns for which an association with the use of the medicinal product is possible based on available data, but this association has not been established yet and needs to be further monitored. Missing information refers to information on the safety of the medicinal product that is currently missing and further information may need to be collected (e.g., on the long-term use of the medicine).

There are no important risks or missing information included in the RMP for Numeta.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks and missing information

There are no important risks or missing information included in this RMP. All risks associated with the use of Numeta are considered fully characterized and appropriately managed with routine risk minimization measures in the product information which are fully integrated into standard clinical practice.

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligations of Numeta.

II.C.2 Other studies in post-authorization development plan

There are no studies required for Numeta.