V.3. Summary of risk minimisation measures

Not applicable.

Part VI: Summary of the risk management plan

Summary of risk management plan for SmofKabiven emulsion for infusion

This is a summary of the risk management plan (RMP) for serials of SmofKabiven emulsion for infusion products. The RMP details important risks of SmofKabiven products, how these risks can be minimised, and how more information will be obtained about SmofKabiven products' risks and uncertainties.

SmofKabiven products' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how SmofKabiven products should be used.

I. The medicine and what it is used for

SmofKabiven is authorised for parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. (See SmPC for the full indication). It contains Glucose, Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Lysine acetate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophan, Tyrosine, Valine, Calcium chloride dihydrate*, Sodium glycerophosphate*, Magnesium sulphate heptahydrate*, Potassium chloride*, Sodium acetate trihydrate*, Zinc sulphate heptahydrate*, Soya-bean oil, medium chain fatty acid, Olive oil, Fish oil (* not included in SmofKabiven/SmofKabiven extra Nitrogen EF) as the active substance and it is given by intravenous infusion.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of SmofKabiven products, together with measures to minimise such risks and the proposed studies for learning more about SmofKabiven products' risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so 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) can help to minimise its risks.

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

II.A List of important risks and missing information

Important risks of SmofKabiven are risks that need special risk management activities to further investigate or minimise 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 SmofKabiven. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

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

II.B Summary of important risks

Not applicable as there is no important identified risk, important potential risk and missing information.

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of SmofKabiven products.

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

There are no studies required for SmofKabiven products.