EU Risk Management Plan for PediSMOF 1, 2 and 3 emulsion/ solution for infusion

Part VI: Summary of the risk management plan

Summary of risk management plan for PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion

This is a summary of the risk management plan (RMP) for PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion. The RMP details important risks of PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion, how these risks can be minimised, and how more information will be obtained about PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion's risks and uncertainties (missing information).

PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion's summary of product characteristics (SmPC) and its package leaflets give essential information to healthcare professionals and patients on how PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion's RMP.

I. The medicine and what it is used for

PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion are authorised in following indications:

PediSMOF 1 emulsion/solution for infusion is indicated to start parenteral nutrition in preterm and term neonates when oral or enteral nutrition is not possible, insufficient, or contraindicated.

PediSMOF 2 emulsion/solution for infusion is indicated for parenteral nutrition in neonates (including preterm and term neonates) and infants up to 2 years of age when oral or enteral nutrition is not possible, insufficient, or contraindicated.

PediSMOF 3 emulsion/solution for infusion is indicated for parenteral nutrition in term neonates, infants, children, and adolescents when oral or enteral nutrition is not possible, insufficient, or contraindicated.

It is available as:

- three-chamber bag (3CB) system and contains partial volumes of amino acids, glucose and lipid emulsion, and is given by intravenous infusion.
- two-chamber bag (2CB) system and contains partial volumes of amino acids and glucose and is given by intravenous infusion.

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

Important risks of PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion's 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed 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 PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion 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 PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion. 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

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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 PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion.

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

There are no studies required for PediSMOF 1 emulsion/solution for infusion, PediSMOF 2 emulsion/solution for infusion and PediSMOF 3 emulsion/solution for infusion.