Summary of Risk Management Plan for PROPOLIPID (propofol)

This is a summary of the risk management plan (RMP) for Propofol Fresenius. The RMP details important risks of Propofol Fresenius, how these risks can be minimised, and how more information will be obtained about Propofol's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Propofol Fresenius RMP.

I. The Medicine and What it is Used For

Propofol LCT 1 % (10 mg/ml) emulsion for injection or infusion, Propofol MCT 1 % (10 mg/ml) emulsion for injection or infusion, Propofol MCT 1 % 10 mg/1 mL emulsion for injection of infusion in pre-filed syringe

is a short-acting intravenous general anaesthetic for:

- induction and maintenance of general anaesthesia in adults and children >1 month
- sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia in adults and children >1 month
- sedation of ventilated patients >16 years of age in the intensive care unit

Propofol LCT 2 % (20 mg/ml) emulsion for injection or infusion, Propofol MCT 2 % (20 mg/ml) emulsion for injection or infusion, Propofol MCT 2 % 20 mg/1 mL emulsion for injection of infusion in pre-filed syringe

is a short-acting intravenous general anaesthetic for:

- induction and maintenance of general anaesthesia in adults and children > 3 years
- sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia in adults and children > 3 years
- sedation of ventilated patients > 16 years of age in the intensive care unit

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Propofol Fresenius, together with measures to minimise such risks and the proposed studies for learning more about Propofol'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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

There is no need for additional risk minimization measures or additional pharmacovigilance activities.

II.A List of important Risks and Missing Information

Important risks of Propofol Fresenius 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 Propofol Fresenius. 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	Neurodevelopmental disorders in children following intrauterine exposure or paediatric use

II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Postauthorisation 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 Propofol Fresenius.

II.C.2 Other Studies in Postauthorisation Development Plan

There are no studies required for Propofol Fresenius.