EU Risk Management Plan

Part VI: Summary of the risk management plan

Summary of risk management plan for Lacosamide Fresenius Kabi 10mg/ml solution for infusion

This is a summary of the risk management plan (RMP) for Lacosamide Fresenius Kabi 10 mg/ml solution for infusion. The RMP details important risks of Lacosamide Fresenius Kabi, how these risks can be minimised, and how more information will be obtained about Lacosamide Fresenius Kabi risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Lacosamide Fresenius Kabi is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.

Lacosamide Fresenius Kabi is indicated as adjunctive therapy

- in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.
- in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy.

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

Important risks of Lacosamide Fresenius Kabi, together with measures to minimise such 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.

If important information that may affect the safe use of Lacosamide Fresenius Kabi is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Lacosamide Fresenius Kabi 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 Lacosamide Fresenius Kabi. 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	• Cardiac adverse events that may be potentially associated with PR interval prolongation or sodium channel modulation
Important potential risks	• None
Missing information	• Pregnant or lactating women • Impact on long-term growth, long-term neurodevelopment, and puberty in pediatric population

II.B Summary of important risks

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

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 Lacosamide Fresenius Kabi.

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

There are no studies, registries or surveys required for Lacosamide Fresenius Kabi.

There are additional pharmacovigilance activities by the reference product Vimpat:

- Registry studies to monitor pregnancy outcomes: participation in and sponsorship of European and International Registry of Antiepileptic Drugs (AEDs) in Pregnancy (EURAP) and in the North American AED Pregnancy Registry (NAAPR).

Activities include provision of requested data from UCB to the registries and regular review of interim outputs from the registries. The protocols for EURAP and NAAPR include possible activities to follow-up on the children.

Prescribers and reporters of pregnancy cases are encouraged to register pregnant women exposed to AEDs into the EURAP and North American AED Pregnancy Registry. References to registries are included on the pregnancy follow-up letter, US Call Center script, and on information for Medical Science Liaisons.

- Ongoing clinical trials in pediatric patients (ie, studies SP848, EP0034, and EP0012) with a follow-up of up to 2 years in SP848/EP0034 and of up to 5 years in EP0012:
  - Endocrinology, body weight, height, calculated body mass index, and head circumferences will be measured in the pediatric studies as per protocol.
  - Neurodevelopmental maturation will be assessed in the pediatric studies as per protocol by the investigator using physical examination and neurodevelopmental validated scales including: Achenbach CBCL, BRIEF/BRIEF-P, Tanner staging

- A remote follow-up development assessment study of neonates who participated in SP0968 (LCM or active comparator treating repeated electroencephalographic neonatal seizures) to collect data regarding the long-term neurocognitive development outcomes of children. The protocol is approved with study planned finish due date Q2/Q3 2025 as per CHMP group of variations including an extension of indication assessment report EMA/99116/2022.