Part VI: Summary of the risk management plan

Summary of risk management plan for *Lacosamide hameln 10mg/ml solution for infusion*

This is a summary of the risk management plan (RMP) for *Lacosamide hameln 10mg/ml solution for infusion.*

The RMP details important risks of *Lacosamide hameln 10 mg/ml solution for infusion,* how these risks can be minimised, and how more information will be obtained about the products' risks and uncertainties (missing information).

The summary of product characteristics (SmPC) for *Lacosamide hameln 10 mg/ml solution for infusion* and the associated package leaflet give essential information to healthcare professionals and patients on how these products should be used.

I. The medicine and what it is used for

Lacosamide hameln 10mg/ml solution for infusion is authorised for the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy (as monotherapy; see SmPC for full indication). It contains lacosamide as the active substance and it is given as IV infusion.

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

Important risks of *Lacosamide hameln 10 mg/ml solution for infusion*, together with measures to minimise such risks and the proposed studies for learning more about the risks associated with treatment with *Lacosamide hameln 10 mg/ml solution for infusion*, 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 a 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 hameln 10mg/ml solution for infusion* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Lacosamide hameln 10 mg/ml 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 *Lacosamide hameln 10 mg/ml 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).

Summary of safety concerns	
Important identified risks	• Cardiac AEs 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 on puberty in paediatric population aged 4 to <16 years

II.B Summary of important risks

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

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 a specific obligation for *Lacosamide hameln 10 mg/ml solution for infusion.*

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

There are no studies required for *Lacosamide hameln 10 mg/ml solution for infusion.*