PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Lacosamide:

Lacosamide 10 mg/ml syrup contains lacosamide. This belongs to a group of medicines called “antiepileptic medicines”.

These medicines are used to treat epilepsy. This is a summary of the risk management plan (RMP) for Lacosamide. The RMP details important risks of Lacosamide, how these risks can be minimised, and how more information will be obtained about Lacosamide's risks and uncertainties (missing information). Lacosamide's summary of product characteristics (SmPC) gives essential information to healthcare professionals and patients on how Lacosamide should be used. Important new concerns or changes to the current ones will be included in updates of Lacosamide's RMP.

This summary of the RMP for Lacosamide should be read in the context of all this information including

I. The medicine and what it's used for:

Lacosamide is used:

- on its own and in association with other antiepileptic medicines in adults, adolescents and children aged 2 years and older to treat a certain type of epilepsy characterised by the occurrence of partial-onset seizure with or without secondary generalisation. In this type of epilepsy, fits first affect only one side of your brain. However, these may then spread to larger areas on both sides of your brain;
- in association with other antiepileptic medicines in adults, adolescents and children aged 4 years and older to treat primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

Important risks of Lacosamide, together with measures to minimize such risks and the proposed studies for learning more about Lacosamide's risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the summary of product characteristics (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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

II.A. List of important risks and missing information

Important risks of Lacosamide are risks that need special risk management activities to further investigate or minimize 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 enough proof of a link with the use of Lacosamide. 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).

Table 2: Summary of safety concerns

Important Identified Risks	• Cardiac adverse events that may be potentially associated with PR interval prolongation and 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 pediatric population

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 specific obligation of Lacosamide.

II.C.2 Other Studies in Post Authorisation Development Plan

There are no studies required for Lacosamide.