PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Lacosamide Tillomed 10 mg/ml solution for infusion (herein referred as Lacosamide infusion):

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

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

I. The medicine and what it is 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 minimise or further characterise the risks

Important risks of lacosamide together with measures to minimise such risks and the proposed studies for learning more about lacosamide'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 PL 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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Lacosamide 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 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	• 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.

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 infusion.

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

There are no studies required for lacosamide infusion.