Part VI: Summary of the risk management plan

Summary of risk management plan for

Lacosamide Grindeks

(Lacosamide)

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

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

Important new concerns or changes to the current ones will be included in updates of Lacosamide Grindeks's RMP.

I. The medicine and what it is used for

Lacosamide Grindeks is authorised for 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. Also, Lacosamide Grindeks is authorised for 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 and also in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy (see SmPC for the full indication). It contains lacosamide as the active substance and it is given by film-coated tablet.

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

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

II.A List of important risks and missing information

Important risks of Lacosamide Grindeks 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 Grindeks. 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 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 newest knowledge.

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 Grindeks.

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

There are no studies required for Lacosamide Grindeks.