Part VI: Summary of the risk management plan

Summary of risk management plan for Lacosamide Krka, Lydraso and Lacosabil

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

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

Important new concerns or changes to the current ones will be included in updates of Lacosamide Krka, Lydraso and Lacosabil's RMP.

I. The medicine and what it is used for

Lacosamide Krka, Lydraso and Lacosabil are authorised for treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy (see SmPC for the full indication). It contains lacosamide as the active substance and it is given orally.

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

Important risks of Lacosamide Krka, Lydraso and Lacosabil, together with measures to minimise such risks and the proposed studies for learning more about Lacosamide Krka, Lydraso and Lacosabil'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 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, including PSUR assessment – 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 Krka, Lydraso and Lacosabil is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Lacosamide Krka, Lydraso and Lacosabil are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Krka, Lydraso and Lacosabil. 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 side effects (Cardiac AEs that may be potentially associated with PR interval prolongation and sodium channel modulation)
	Suicidality
	Dizziness
Important potential risks	Potential for bad side effect on liver (Potential for hepatotoxicity)
	Potential for worsening of seizures
	Potential for abuse (Potential for abuse as a CNS-active product)
	Potential for unapproved use (Potential for off-label use of a loading dose in acute conditions such as status epilepticus)
Missing information	Pregnant or lactating women
	Impact on long-term growth, long-term neurodevelopment, and on puberty in pediatric population aged 4 to <16 years

II.B Summary of important risks

Pregnant or lactating women	
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Participation in EURAP – An International Registry of Antiepileptic Drugs and Pregnancy (Category 3) See section II.C of this summary for an overview of the post-authorisation development plan.

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 Krka, Lydraso and Lacosabil.

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

Participation in EURAP – An International Registry of Antiepileptic Drugs and Pregnancy (Category 3)

Purpose of the study: To collect data on lacosamide use in pregnancy or breastfeeding women.

Activities include provision of requested data from Krka, d. d., Novo mesto, to the EURAP registry and regular review of interim outputs from the registry.

Prescribers and reporters of pregnancy cases are actively encouraged to register pregnant women exposed to anti-epileptic drugs into the EURAP when requesting follow-up on pregnancy cases.