Part VI: Summary of the risk management plan

Summary of risk management plan for Lacosamide Vivanta (Lacosamide)

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

The Summaries of Product Characteristics (SmPC) and corresponding Package Leaflets (PL) give essential information to healthcare professionals and patients on how Lacosamide Vivanta film-coated tablets & solution for infusion should be used.

I. The medicine and what it is used for

Lacosamide is indicated as 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.

Lacosamide is indicated as 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.
- in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy.

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 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.

If important information that may affect the safe use of Lacosamide 10 mg/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 are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

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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. 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 AEs that may be potentially associated with PR interval prolongation or sodium channel modulation
Important potential risks	• None
Missing information	• Pregnancy 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

The safety information in the proposed Product Information is aligned to that of 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

Additional pharmacovigilance activities include the following:

Participation in pregnancy registries (European and International Registry of AEDs in Pregnancy [EURAP]: Prescribers and patients reporting pregnancy cases are encouraged by MSN/Vivanta generics to register pregnant women exposed to Antiepileptic Drugs (AEDs) into the European Registry of Antiepileptic Drugs and Pregnancy (EURAP). Data from the EURAP registry should be reviewed on an ongoing basis as part of routine pharmacovigilance activities.

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