
EU Risk Management Plan for Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion

Part VI: Summary of the risk management plan

Summary of risk management plan for Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion (Levetiracetam)

This is a summary of the risk management plan (RMP) for Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion. The RMP details important risks of Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion, how these risks can be minimised, and how more information will be obtained about Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion's risks and uncertainties (missing information).

Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion's RMP.

I. The medicine and what it is used for

Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion is authorised as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion is indicated as adjunctive therapy:

- in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy.
- in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy.
- in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.

Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

It contains levetiracetam as the active substance and is administered by intravenous route.

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

Important risks of Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion, together with measures to minimise such risks and the proposed studies for learning

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more about Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion'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 Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 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 Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for 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 Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for 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 for patients aged 1 month and older	
Important identified risks	None
Important potential risks	None
Missing information	Long-term effects on learning, intelligence, growth, endocrine function, puberty, and childbearing potential in children with epilepsy or in children exposed in utero

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Levetiracetam Kabi; RMP version 0.3

II.B Summary of important risks

The safety information in the Product Information is aligned to the reference medicinal product (Keppra 100 mg/ml concentrate for solution for infusion).

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 Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion.

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

There are no studies required for Levetiracetam Kabi 5 mg/ml solution for infusion and Levetiracetam Kabi 10 mg/ml solution for infusion.