Part VI: Summary of the risk management plan

Summary of risk management plan for Levetiracetam Accord 100 mg/ml; oral solution (Levetiracetam)

This is a summary of the risk management plan (RMP) for Levetiracetam Accord 100 mg/ml; oral solution. The RMP details important risks of Levetiracetam Accord 100 mg/ml; oral solution, how these risks can be minimised, and how more information will be obtained about Levetiracetam Accord 100 mg/ml; oral solution's risks and uncertainties (missing information).

Levetiracetam Accord 100 mg/ml; oral solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Levetiracetam Accord 100 mg/ml; oral solution should be used.

Important new concerns or changes to the current ones will be included in updates of Levetiracetam Accord 100 mg/ml; oral solution RMP.

I. The medicine and what it is used for

Levetiracetam Accord is indicated 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 Accord is indicated as adjunctive therapy

- in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents, children and infants from 1 month 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.

It contains levetiracetam as the active substance and it is given by oral route.

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

Important risks of Levetiracetam Accord 100 mg/ml; oral solution, together with measures to minimise such risks and the proposed studies for learning more about Levetiracetam Accord 100 mg/ml; oral solution'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 (as required) and signal management activity, 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 Accord 100 mg/ml; oral solution is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Levetiracetam Accord 100 mg/ml; oral solution 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 Levetiracetam Accord 100 mg/ml; oral solution. 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).

Important identified risks	• Suicidality in patients 'aged 4 years and older' • Abnormal behaviour • Blood dyscrasias
Important potential risks	• Seizure worsening
Missing information	• Long-term effects in children on learning, intelligence, growth, endocrine function, puberty, and childbearing potential • Decreased bone mineral density after prolonged levetiracetam exposure in patients 'aged 4 years and older'

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 Levetiracetam Accord 100 mg/ml; oral solution.

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

There are no studies required for Levetiracetam Accord 100 mg/ml; oral solution.