Part VI: Summary of the risk management plan

Summary of risk management plan for Tilamir 250 mg, 500 mg, 750 mg, 1000 mg film-coated tablets (Levetiracetam)

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

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

I. The medicine and what it is used for

Tilamir 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.

- 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 (see SmPC for the full indication). It contains levetiracetam 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 Tilamir, together with measures to minimise such risks and the proposed studies for learning more about Tilamir'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.

If important information that may affect the safe use of Tilamir is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tilamir 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 Tilamir. 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 for patients aged 1 month to less than 4 years	
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
Summary of safety concerns for patients aged 4 years 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 • Worsening of seizure control during pregnancy

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 Tilamir.

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

There are no studies required for Tilamir.