Part VI: Summary of the risk management plan

Summary of risk management plan for Peleikos (Lacosamide)

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

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

Important new concerns or changes to the current ones will be included in updates of Peleikos's RMP.

I. The medicine and what it is used for

Peleikos 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. Peleikos is authorised 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 and in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy (see SmPC for the full indication). It contains Lacosamide as the active substance and it is given by oral route of administration.

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

Important risks of Peleikos, together with measures to minimise such risks and the proposed studies for learning more about Peleikos'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 Peleikos is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Peleikos 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 Peleikos. 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 adverse events (AEs) that may be potentially associated with PR interval prolongation and sodium channel modulation
Important potential risks	• None
Missing information	• Impact on long-term growth, long-term neurodevelopment, and puberty in paediatric population • Pregnant or lactating women

II.B Summary of important risks

Missing information: Use in pregnancy and during breast-feeding	
Additional pharmacovigilance activities	Additional pharmacovigilance activities: International Registry of Antiepileptic Drugs and Pregnancy (EURAP). 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 Peleikos.

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

International Registry of Antiepileptic Drugs and Pregnancy (EURAP), category 3

Purpose of the study: the primary goal of this prospective observational study of pregnancies with antiepileptic drugs is to compare the risk of major congenital malformations following maternal intake of different antiepileptic drugs and their combinations. Secondary objectives include the evaluation of any specific pattern of foetal abnormalities, dose-effect relationships and other risk factors.