Part VI: Summary of the risk management plan

Summary of risk management plan for Eslicarbazepine Acetate

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

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

I. The medicine and what it is used for

Eslicarbazepine acetate is authorised for monotherapy in the treatment of partial-onset seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy and adjunctive therapy in adults, adolescents and children aged above 6 years, with partial-onset seizures with or without secondary generalisation (see SmPC for the full indication). It contains eslicarbazepine acetate as the active substance and it is given by oral administration as tablets. Eslicarbazepine acetate tablets are available in strengths of 200 mg, 400 mg, 600 mg and 800 mg.

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

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

II.A List of important risks and missing information

Important risks of eslicarbazepine acetate 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 eslicarbazepine acetate. 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	• Hyponatremia • Cutaneous adverse reactions
Important potential risks	• Thyroid function changes • International Normalised Ratio (INR) and activated Partial Thromboplastin Time (aPTT) increase • Cardiovascular/cerebrovascular ischemia • Potential for suicidality as anti-epileptic drug • Bone disorders
Missing information	• Exposure during pregnancy • Pediatric population (<2 years of age) • Elderly population • Long term effects on brain development, learning, intelligence, growth, endocrine function, puberty and childbearing potential in children

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 eslicarbazepine acetate.

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

There are no studies required for eslicarbazepine acetate.