Part VI: Summary of the risk management plan

Summary of risk management plan for Amifampridine SERB

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

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

This summary of the RMP for Amifampridine SERB should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Amifampridine SERB is authorised for symptomatic treatment of Lambert Eaton myasthenic syndrome (LEMS) in adults (see SmPC for the full indication). It contains amifampridine as the active substance and it is given orally as tablet.

Further information about the evaluation of Amifampridine SERB's benefits can be found Amifampridine SERB's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/amifampridine-serb.

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

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

II.A List of important risks and missing information

Important risks of Amifampridine SERB 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 Amifampridine SERB. 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 risk	• Seizures • Food-drug interaction
Important potential risk	• Movement disorders • Cardiac toxicity including QTc prolongation. • Peripheral vascular disorders/Raynaud's phenomenon • Respiratory disorders including bronchospasm. • Hepatotoxicity • Serious gastrointestinal conditions • Risk of nerve sheath tumour development (Schwannoma in rats)
Missing information	• Limited information on use in patients with renal impairment • Lack of information on use in patients with hepatic disease • Lack of information on use during pregnancy and lactation • Lack of information on potential drug-drug interactions (DDI) (including QTc prolonging drugs, seizure threshold reducing drugs, atropinic and cholinergic drugs, and depolarizing and non-depolarizing muscle relaxants) • Lack of photosafety data

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 Amifampridine SERB.

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

There are no studies required for Amifampridine SERB.