Summary of risk management plan for Fampridine Newbury (Fampridine)

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

Fampridine Newbury's SmPC and its Patient Information Leaflet (PIL) give essential information to Healthcare Professionals and patients on how Fampridine Newbury should be used. This summary of the RMP for Fampridine Newbury 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 Fampridine Newbury 's RMP.

I. The medicine and what it is used for

Fampridine Newbury is authorised for the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4-7) (see SmPC for the full indication). It contains fampridine 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 Fampridine Newbury, together with measures to minimise such risks and the proposed studies for learning more about Fampridine Newbury '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 PIL 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 public (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 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 Fampridine Newbury is not yet available, it is listed under ‘missing information’.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.A List of important risks and missing information

Important risks of Fampridine Newbury 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 Fampridine Newbury. 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	None
Important potential risks	None
Missing information	None

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 Fampridine Newbury.

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

There are no studies required for Fampridine Newbury.