

## Summary of risk management plan for Fampridine STADA 10 mg prolonged-release tablets (Fampridine)

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

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

### **I. The medicine and what it is used for**

Fampridine STADA 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 orally.

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

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

## ***II.A List of important risks and missing information***

Important risks of Fampridine STADA 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 STADA. 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);

<b>Summary of safety concerns</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

## ***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 Fampridine STADA.

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

There are no studies required for Fampridine STADA.