Summary of the Risk Management Plan for Fampyra™ (Fampridine)

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The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Fampyra™ is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Fampyra™ in Switzerland is the "Arzneimittelinformation / Information sur le medicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Biogen Switzerland AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Fampyra™.

1. The medicine and what it is used for

FAMPYRA is authorised for the improvement of walking in adult patients with multiple sclerosis with walking disability (Expanded Disability Status Scale score [EDSS] of 4 to 7) (see "Arzneimittelinformation / Information sur le medicament" for the full indication). It contains fampridine as the active substance, and it is given orally by prolonged-release 10 mg tablets.

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

Important risks of FAMPYRA, together with measures to minimise such risks and the proposed studies for learning more about the risks of FAMPYRA, 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, respectively;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen to ensure that the medicine is used correctly; and
- 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 FAMPYRA is not yet available, it is listed under 'missing information' below.

2.1. List of important risks and missing information

Important risks of FAMPYRA 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 categorised as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of FAMPYRA. 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 needs to be collected (e.g., on the long-term use of the medicine).

There are no important risks or areas of missing information associated with FAMPYRA treatment.

2.2. Summary of important risks

There are no important identified risks, important potential risks, or areas of missing information associated with FAMPYRA treatment.

2.3. Post-authorisation development plan

2.3.1. Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation for FAMPYRA.

2.3.2. Other studies in post-authorisation development plan

There are no studies required for FAMPYRA.