Part VI: Summary of the Risk Management Plan

Summary of risk management plan for foslevodopa/foscarbidopa

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

Foslevodopa/foscarbidopa summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how foslevodopa/foscarbidopa should be used.

I The Medicine and What it Is Used For

Foslevodopa/foscarbidopa is authorised for treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results (see SmPC for the full indication). It contains a 1:20 mixture (by mass) of foscarbidopa (CDP4' 12 mg/mL) and foslevodopa (LDP4' 240 mg/mL) as the active substance and it is given as a continuous subcutaneous infusion.

II Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of foslevodopa/foscarbidopa, together with measures to minimise such 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 (PL) and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging including instruction of use (IFUs);
- 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 the case of foslevodopa/foscarbidopa, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of Important Risks and Missing Information

Important risks of foslevodopa/foscarbidopa are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 foslevodopa/foscarbidopa. 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	Infusion site events (infusion site infections and serious infusion site reactions)
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

Important identified risk: Infusion site events (infusion site infections and serious infusion site reactions)	
Evidence for linking the risk to the medicine	Clinical trial data and literature
Risk factors and risk groups	• Failure to follow aseptic techniques • Health care provider/patient lack of experience with subcutaneous infusion-related therapies • Patients with advanced PD associated with motor symptoms (tremors, rigidity, etc.,) are more likely to have difficulties using the drug delivery system as intended • Other comorbidities including diabetes, impaired immune function and thinning of the skin especially in the elderly population
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.4 Special warnings and precautions for use

	SmPC Section 4.8 Undesirable effects PL Section 2 What you need to know before you use foslevodopa/foscarbidopa: The SmPC and PL provide reference to device IFUs. Device IFUs will be provided to patients and HCPs. Additional risk minimisation measures: Patient Educational Material
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Observational cohort study among individuals with PD and use of ABBV-951 See Section II.C of this summary for an overview of the post authorisation development plan.

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 foslevodopa/foscarbidopa.

II.C.2 Other Studies in Post-Authorisation Development Plan

Observational cohort study to evaluate the effectiveness of additional risk minimisation measures for foslevodopa/foscarbidopa in the treatment of advanced Parkinson's disease.