In alignment with the safety concerns of the innovator's RMP (Velcade®), there are no important identified risk, important potential risks, and missing information for bortezomib Hospira.

Summary of risk management plan for Bortezomib Hospira 1 mg, 2.5 mg, 3 mg, 3.5 mg powder for solution for injection (Bortezomib)

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

Bortezomib Hospira powder for solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to HCPs and patients on how Bortezomib Hospira powder for solution for injection should be used.

This summary of the RMP for bortezomib Hospira powder for solution for injection 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 EPAR.

Important new concerns or changes to the current ones will be included in updates of bortezomib Hospira powder for solution for injection's RMP.

I. The Medicine and What It Is Used For

Bortezomib Hospira as monotherapy or in combination with pegylated liposomal doxorubicin or dexamethasone is indicated for the treatment of adult patients with progressive multiple myeloma who have received at least 1 prior therapy and who have already undergone or are unsuitable for haematopoietic stem cell transplantation (see SmPC for the full indication). It contains bortezomib as the active substance and it is given by intravenous or subcutaneous route of administration.

Bortezomib Hospira in combination with melphalan and prednisone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

Bortezomib Hospira in combination with dexamethasone, or with dexamethasone and thalidomide, is indicated for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

Bortezomib Hospira in combination with rituximab, cyclophosphamide, doxorubicin and prednisone is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.

Further information about the evaluation of bortezomib Hospira powder for solution for injection's benefits can be found in bortezomib Hospira powder for solution for injection's

EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage link to the EPAR summary landing page:

https://www.ema.europa.eu/en/medicines/human/EPAR/bortezomib-hospira.

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

Important risks of bortezomib Hospira, together with measures to minimise such risks and the proposed studies for learning more about bortezomib Hospira'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 events is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A. List of Important Risks and Missing Information

In alignment with the safety concerns of the innovator's RMP (Velcade®), there are no important identified risk, important potential risks, and missing information for bortezomib Hospira.

Table 1. List of important risks and missing information

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 bortezomib Hospira.

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 bortezomib.

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

There are no studies required for bortezomib Hospira.