Summary of risk management plan for Bortezomib Krka, Bortezomib TAD (bortezomib)

This is a summary of the risk management plan (RMP) for Bortezomib Krka, Bortezomib TAD. The RMP details important risks of Bortezomib Krka, Bortezomib TAD and how more information will be obtained about Bortezomib Krka's, Bortezomib TAD's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Bortezomib Krka's, Bortezomib TAD's RMP.

I. The medicine and what it is used for

Bortezomib Krka, Bortezomib TAD is authorised for treatment of adult patients with progressive multiple myeloma, treatment of adult patients with previously untreated multiple myeloma and for treatment of adult patients with previously untreated mantle cell lymphoma (see SmPC for the full indication). It contains bortezomib as the active substance. 1 mg powder for solution for injection is given intravenous only and 3.5 mg powder for solution for injection is available for intravenous or subcutaneous administration.

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

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

II.A List of important risks and missing information

Important risks of Bortezomib Krka, Bortezomib TAD 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 Bortezomib Krka, Bortezomib TAD. 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.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 Bortezomib Krka, Bortezomib TAD.

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

There are no studies required for Bortezomib Krka, Bortezomib TAD.