

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Bortezomib 3.5 mg Powder for Solution for Injection

This is a summary of the risk management plan (RMP) for Bortezomib 3.5 mg Powder for Solution for Injection. The RMP details important risks of Bortezomib, how these risks can be minimised, and how more information will be obtained about Bortezomib risks and uncertainties (missing information).

Bortezomib 3.5 mg Powder for Solution for Injection Summary of Product Characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Bortezomib 3.5 mg Powder for Solution for Injection should be used.

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

Bortezomib 3.5 mg Powder for Solution for Injection 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.

Bortezomib 3.5 mg Powder for Solution for Injection 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 3.5 mg Powder for Solution for Injection 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 3.5 mg Powder for Solution for Injection 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.

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

Important risks of Bortezomib, 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 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 analyzed, 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***

Important risks of Bortezomib 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. 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>	
<b>Important identified risks</b>	• None
<b>Important potential risks</b>	• None
<b>Missing information</b>	• 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.

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

There are no studies required for Bortezomib.