Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Bortezomib Glenmark 2.5 mg/mL Solution for Injection (Bortezomib)

This is a summary of the risk management plan (RMP) for Bortezomib Glenmark 2.5 mg/mL Solution for Injection. The RMP details important risks of Bortezomib Glenmark 2.5 mg/mL Solution for Injection, how these risks can be minimised, and how more information will be obtained about Bortezomib Glenmark 2.5 mg/mL Solution for Injection risks and uncertainties (missing information).

Bortezomib Glenmark 2.5 mg/mL Solution for Injection summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Bortezomib Glenmark 2.5 mg/mL Solution for Injection should be used.

Important new concerns or changes to the current ones will be included in updates of Bortezomib Glenmark 2.5 mg/mL Solution for Injection RMP.

I. The medicine and what it is used for

Bortezomib Glenmark 2.5 mg/mL Solution for Injection is authorised for the following:

- Bortezomib 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 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 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 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.

It contains bortezomib as the active substance and it is administered via intravenous or subcutaneous injection.

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

Important risks of Bortezomib Glenmark 2.5 mg/mL Solution for Injection, together with measures to minimise such risks and the proposed studies for learning more about Bortezomib Glenmark 2.5 mg/mL Solution for Injection 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 PL 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.

II.A. List of important risks and missing information

Important risks of Bortezomib Glenmark 2.5 mg/mL Solution for Injection 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 Glenmark 2.5 mg/mL Solution for Injection. 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 risk(s)	• None
Important potential risk(s)	• None
Missing information	• None

II.B. Summary of important risk

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 Glenmark 2.5 mg/mL Solution for Injection.

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

There are no studies required for Bortezomib Glenmark 2.5 mg/mL Solution for Injection.