

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR BORTEZOMIB EVER PHARMA 2.5 MG/ML SOLUTION FOR INJECTION (BORTEZOMIB)

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

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

I. The medicine and what it is used for

Bortezomib EVER Pharma is authorised:

- As monotherapy or in combination with pegylated liposomal doxorubicin or dexamethasone, 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.
- In combination with melphalan and prednisone, for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

- In combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.
- In combination with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation (see SmPC for the full indication).

It contains bortezomib as the active substance and it is given as a solution for injection.

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

Important risks of Bortezomib EVER Pharma, together with measures to minimise such risks and the proposed studies for learning more about Bortezomib EVER Pharma'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.

If important information that may affect the safe use of Bortezomib EVER Pharma is not yet available, it is listed under '*missing information*' below.

II.A List of important risks and missing information

Important risks of Bortezomib EVER Pharma 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 EVER Pharma. 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 a specific obligation for Bortezomib EVER Pharma.

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

There are no studies required for Bortezomib EVER Pharma.