6 Part VI: Summary of the risk management plan (RMP) Bendamustine hydrochloride, 2.5 mg/ml, Powder for concentrate for solution for infusion

This is a summary of the RMP for bendamustine hydrochloride powder for concentrate for solution for infusion 2.5 mg/ml. The RMP details important risks of bendamustine hydrochloride powder for concentrate for solution for infusion, how these risks can be minimized, and how more information will be obtained about bendamustine hydrochloride powder for concentrate for solution for infusion's risks and uncertainties (missing information).

Bendamustine hydrochloride powder for concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how bendamustine hydrochloride powder for concentrate for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of bendamustine hydrochloride powder for concentrate for solution for infusion's RMP.

6.1 Part VI: I. The medicine and what it is used for

Bendamustine hydrochloride powder for concentrate for solution for infusion is a medicine which is used for the treatment of certain types of cancer (cytotoxic medicine).

Bendamustine hydrochloride powder for concentrate for solution for infusion is used alone (monotherapy) or in combination with other medicines for the treatment of the following forms of cancer:

- chronic lymphocytic leukemia (cancer of the white blood cells) in cases where fludarabine combination chemotherapy is not appropriate for you,
- non-Hodgkin’s lymphomas (cancer of lymphocytes, a type of white blood cell), which had not, or only shortly, responded to prior rituximab treatment,
- Multiple myeloma (cancer of plasma cells, a type of white blood cell) in cases where thalidomide or bortezomib containing therapy is not appropriate for you.

6.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of bendamustine hydrochloride powder for concentrate for solution for infusion, together with measures to minimize such risks are outlined below.

Measures to minimize 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 HCPs;
- Important advice on the medicine’s packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (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 bendamustine hydrochloride powder for concentrate for solution for infusion is not yet available, it is listed under 'missing information' below.

6.2.1 Part VI – II.A: List of important risks and missing information

Important risks of bendamustine hydrochloride powder for concentrate for solution for infusion are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 bendamustine hydrochloride powder for concentrate for solution for infusion. 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).

Table 7-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Myelosuppression
	Infections (including opportunistic infections of herpes zoster, cytomegalovirus, Pneumocystis jirovecii pneumonia)
	Hepatitis B reactivation
	Hepatic failure
	Severe skin reactions
	Cardiac disorders of cardiac failure, myocardial infarction, and atrial fibrillation
	Tumor lysis syndrome
	Renal failure
	Anaphylaxis
	Secondary malignancies of myelodysplastic syndrome and acute myeloid leukemia
Important potential risks	None
Missing information	Exposure during pregnancy and lactation

6.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

6.2.3 Part VI – II.C: Post-authorization development plan

6.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of bendamustine hydrochloride powder for concentrate for solution for infusion.

6.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for bendamustine hydrochloride powder for concentrate for solution for infusion.