PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Bendamustine medac 2.5 mg/ml powder for concentrate for solution for infusion (bendamustine hydrochloride)

This is a summary of the risk management plan (RMP) for Bendamustine medac. The RMP details important risks of Bendamustine medac, how these risks can be minimised, and how more information will be obtained about Bendamustine medac's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Bendamustine medac's RMP.

I. The medicine and what it is used for

Bendamustine medac is authorised for the treatment of chronic lymphocytic leukaemia, indolent non-Hodgkin's lymphomas, and multiple myeloma (see SmPC for the full indication). It contains bendamustine hydrochloride as the active substance and it is given by infusion.

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

Important risks of Bendamustine medac, together with measures to minimise such risks and the proposed studies for learning more about Bendamustine medac'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 events is collected continuously and regularly analysed, 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 medac is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Bendamustine medac 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 Bendamustine medac. 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	Myelosuppression Infections (including opportunistic infections of herpes zoster, cytomegalovirus, *Pneumocystis jirovecii* pneumonia) Hepatitis B reactivation
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 with are conditions of the marketing authorisation or specific obligation of Bendamustine medac.

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

There are no studies required for Bendamustine medac.