RIBOMUSTIN®

Pulver für ein Konzentrat zur Herstellung einer Infusionslösung (i.v.),

Durchstechflaschen zu 25,0 mg und 100,0 mg Bendamustinhydrochlorid (entsprechend 22,7 mg und 90,8 mg Bendamustin).

Zul.-Nr. 58'816

Public Risk Management Plan (RMP) Summary

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of Ribomustin® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the 'Arzneimittelinformation / Information sur le médicament' approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Ribomustin® in Switzerland is the 'Arzneimittelinformation / Information sur le médicament' (see www.swissmedic.ch) approved and authorized by Swissmedic. CPS Cito Pharma Services GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of Ribomustin®.

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Document Version 1.0

Based on EU RMP version (please note that the brand name in the summary of the risk management plan is the one marketed in the EEA (Levact®), while in Switzerland Bendamustine hydrochloride's brand name shall be Ribomustin®)

Based on: EU-RMP Version 9.1 dated from 27.10.2023

PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for bendamustine hydrochloride

This is a summary of the risk management plan (RMP) for bendamustine. The RMP details important risks of bendamustine and how these risks can be minimized.

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

Important new concerns or changes to current concerns will be included in updates of bendamustine's RMP.

I. The medicine and what it is used for

Bendamustine is an alkylating antitumor agent with bifunctional alkylating activity. Bendamustine is authorized for first-line treatment of chronic lymphocytic leukemia (CLL), indolent and/or low-grade non-Hodgkin's lymphoma (NHL) that has progressed following treatment(s) with rituximab or a rituximab-containing regimen and front line treatment of multiple myeloma (MM) (Durie-Salmon stage II with progress or stage III) in combination with prednisone (see SmPC for the full indication). The route of administration is IV infusion.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of bendamustine, 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 SmPC addressed to patients and healthcare professionals;
- 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 minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Updated 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 bendamustine is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of bendamustine are risks that need special risk management activities to further investigate or minimize 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. 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 14 List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

II.C Postauthorization development plan

There are no other studies required for bendamustine.