Summary of the Risk Management Plan (RMP)

BiCNU®

Carmustine 100 mg Powder and solvent for solution for infusion

Product concerned (brand name): BiCNU®
Active substance: Carmustine
Strength: 100 mg Powder and solvent for solution for infusion
Pharmaceutical form: Powder and solvent for infusion solution
Version number: 7.0
Date: 07 Jun 2022
Marketing Authorisation Holder: IDEOGEN AG, Freienbach

Disclaimer:
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 BiCNU 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 BiCNU in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. IDEOGEN AG, Freienbach is fully responsible for the accuracy and correctness of the content of the published summary RMP of BiCNU.

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LIST OF ABBREVIATIONS

EU:	European Union
HIV:	Human Immunodeficiency Virus
HL:	Hodgkin's Lymphoma
NO:	Nitricoxide
NHL:	Non-Hodgkin's lymphoma
RMP:	Risk Management Plan
UK:	United Kingdom
WHO:	World Health Organization

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for BiCNU (Carmustine)

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

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

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

I. The medicine and what it is used for

BiCNU is indicated as single agent or in established combination therapy with other approved chemotherapeutic agents for salvage therapy in case of relapsed Grade III and IV Glioma, Hodgkin's disease and Non-Hodgkin's lymphoma (NHL) (see SmPC for the full indication). It contains carmustine as the active substance and it is given by intravenous route of administration.

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

Important risks of BiCNU, together with measures to minimise such risks and the proposed studies for learning more about BiCNU'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 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 Title 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 reactions is collected continuously and regularly analysed, including periodic safety update report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of BiCNU 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 BiCNU. 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	None
Important potential risk	None
Missing information	None

II.B Summary of important risks

There are no important identified risks, important potential risks, or missing information in this RMP.

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 BiCNU.

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

There are no studies required for BiCNU.