Part VI: Summary of the risk management plan

Summary of risk management plan for Carmustine 100 mg Powder and solvent for solution for infusion

This is a summary of the risk management plan (RMP) for Carmustine 100 mg Powder and solvent for solution for infusion. The RMP details important risks of Carmustine 100 mg Powder and solvent for solution for infusion, how these risks can be minimised, and how more information will be obtained about Carmustine 100 mg Powder and solvent for solution for infusion's risks and uncertainties (missing information).

Carmustine 100 mg Powder and solvent for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Carmustine 100 mg Powder and solvent for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Carmustine 100 mg Powder and solvent for solution for infusion's RMP.

I. The medicine and what it is used for

Carmustine 100 mg Powder and solvent for solution for infusion is authorised as palliative therapy as a single agent or in established combination therapy with other approved chemotherapeutic agents (see SmPC for the full indication). It contains carmustine as the active substance and it is given by intravenous administration.

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

Important risks of Carmustine 100 mg Powder and solvent for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Carmustine 100 mg Powder and solvent for solution for infusion'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;

Summary of safety concerns	
Important identified risks	Pulmonary toxicity [including in paediatric population] Bone marrow toxicity Hepatotoxicity Nephrotoxicity Gastrointestinal toxicity including nausea and vomiting

- The authorised pack size — the amount of medicine in a pack is chosen 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 Carmustine 100 mg Powder and solvent for solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Carmustine 100 mg Powder and solvent for solution for infusion 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 Carmustine 100 mg Powder and solvent 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);

Summary of safety concerns	
	Injection site reaction including extravasation hazard
Important potential risks	Secondary malignancies Reproduction toxicity including embryotoxicity, teratogenicity and impaired fertility
Missing information	Use during pregnancy and lactation

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 specific obligation of Carmustine 100 mg Powder and solvent for solution for infusion.

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

There are no studies required for Carmustine 100 mg Powder and solvent for solution for infusion.