Summary of risk management plan for PHELINUN 50 mg Powder and Solvent for Concentrate for Solution for Infusion and PHELINUN 200 mg Powder and Solvent for Concentrate for Solution for Infusion (Melphalan)

This is a summary of the risk management plan (RMP) for PHELINUN 50 mg Powder and Solvent for Concentrate for Solution for Infusion and PHELINUN 200 mg Powder and Solvent for Concentrate for Solution for Infusion (hereinafter to as PHELINUN). The RMP details important risks of PHELINUN, how these risks can be minimised, and how more information will be obtained about PHELINUN's risks and uncertainties (missing information).

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

This summary of the RMP for PHELINUN should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

PHELINUN is authorised for (see SmPC for the full indication):

- the treatment of multiple myeloma, malignant lymphoma (Hodgkin's, non-Hodgkin's lymphoma), acute lymphoblastic and myeloblastic leukemia, childhood neuroblastoma, ovarian cancer, and mammary adenocarcinoma;
- in combination with other cytotoxic drugs in adult as reduced intensity conditioning (RIC) treatment prior to allogeneic haematopoietic stem cell transplantation (HSCT) in malignant haematological diseases.
- in combination with other cytotoxic drugs in paediatric population as conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (HSCT) in haematological diseases:
    - Myeloablative conditioning (MAC) treatment in case of malignant haematological diseases;
    - RIC treatment in case of non-malignant haematological diseases.
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It contains melphalan as the active substance and it is given by intravenous infusion.

Further information about the evaluation of PHELINUN's benefits can be found in PHELINUN's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/phelinun.

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

Not Applicable. No safety concerns have been identified for PHELINUN.

II.A List of important risks and missing information

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable. No safety concerns have been identified for PHELINUN.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are part of the conditions of the authorisation of PHELINUN.

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

There are no studies required for PHELINUN.