Part VI: Summary of the risk management plan for Merocarb 500 mg, powder for solution for injection/infusion and Merocarb 1000 mg, powder for solution for injection/infusion

This is a summary of the risk management plan (RMP) for Merocarb 500 mg, powder for solution for injection/infusion and Merocarb 1000 mg, powder for solution for injection/infusion. The RMP details important risks of Merocarb 500 mg, powder for solution for injection/infusion, and Merocarb 1000 mg, powder for solution for injection/infusion how these risks can be minimised, and uncertainties (missing information). Merocarb 500 mg, powder for solution for injection/infusion and Merocarb 1000 mg, powder for solution for injection/infusion Summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how the drugs should be used.

I. The medicine and what it is used for

Merocarb, powder for solution for injection/infusion is indicated for the treatment of:

- Severe pneumonia, including hospital and ventilator-associated pneumonia;
- Broncho-pulmonary infections in cystic fibrosis;
- Complicated urinary tract infections;
- Complicated intra-abdominal infections;
- Intra- and post-partum infections;
- Complicated skin and soft tissue infections;
- Acute bacterial meningitis.

Merocarb , powder for solution for injection/infusion may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.
Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

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

Important risks of Merocarb, powder for solution for injection/infusion, together with measures to minimise such risks, are outlined below.
Measures to minimise the risks identified: none
No additional risk minimisation measures are proposed.

In addition to these measures, routine pharmacovigilance activities including adverse reactions reporting, PSUR, medical literature monitoring, and other activities as required under EU legislation, are made.

If important information that may affect the safe use of Merocarb, powder for solution for injection/infusion is not yet available, it will be list under missing information.

II. A. List of important risks and missing information

Important risks of Merocarb, powder for solution for injection/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 Merocarb, powder for solution for injection/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.

Summary of safety concerns	
Important identified risks	None
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 Meronem® IV 500mg and Meronem 1000 mg, powder for solution for injection/infusion with the comments from Summary of assessment per safety concerns from the HaRP Assessment Report of meropenem dated 29 April 2020 published by CMDh.

II. C. Post- authorisation development plan

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

Not applicable.

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

Not applicable.