Summary of risk management plan for [Meropenem] 500mg, 1g Powder for solution for injection/infusion

This is a summary of the risk management plan (RMP) [Meropenem] 500mg, 1g Powder for solution for injection/infusion. The RMP details important risks of [Meropenem] 500mg, 1g Powder for solution for injection/infusion, how these risks can be minimised, and how more information will be obtained about [Meropenem] 500mg, 1g Powder for solution for injection/infusion risks and uncertainties (missing information).

[Meropenem] 500mg, 1g Powder for solution for injection/infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Meropenem] 500mg, 1g Powder for solution for injection/infusion should be used.

Important new concerns will be included in updates of [Meropenem] 500mg, 1g Powder for solution for injection/infusion's RMP.

I. The medicine and what it is used for

[Meropenem] 500mg, 1g Powder for solution for injection/infusion contains the active substance meropenem and belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections.

[Meropenem] 500mg, 1g Powder for solution for injection/infusion is used to treat the following in adults and children over 3 months of age:
• 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
[Meropenem] 500mg, 1g 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. [Meropenem] 500mg, 1g Powder for solution for injection/infusion may be used to treat bacterial infection of the blood which might be associated with, any of the infections listed above.

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

Important risks of [Meropenem] 500mg, 1g Powder for solution for injection/infusion together with measures to minimise such risks and the proposed studies for learning more about [Meropenem] 500mg, 1g Powder for solution for injection/infusion, 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;
- The authorised 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of [Meropenem] 500mg, 1g Powder for solution for injection/infusion 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 [Meropenem] 500mg, 1g 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 (e.g. on the long-term use of the medicine).

List of important risks and missing information	
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.

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 [Meropenem] 500mg, 1g Powder for solution for injection/infusion.

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

There are no studies required for [Meropenem] 500mg, 1g Powder for solution for injection/infusion.