Summary of risk management plan for Cefotaxime hameln, 1g, 2g, powder for solution for injection or infusion (Cefotaxime)

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

Cefotaxime hameln's product information gives essential information to healthcare professionals and patients on how Cefotaxime hameln should be used.

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

I. The medicine and what it is used for

Cefotaxime hameln is indicated in the treatment of the following severe infections either when known or thought very likely to be caused by bacteria that are susceptible to cefotaxime:

- Bacterial pneumonia
- Complicated infections of the urinary tract including pyelonephritis
- Severe skin and soft tissue infections
- Genital infections, including gonorrhoea
- Intra-abdominal infections (such as peritonitis)
- Bacterial meningitis
- Endocarditis
- Borreliosis

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Perioperative prophylaxis. For surgical operations with increased risk of infections with anaerobic pathogens, e.g. colorectal surgery, a combination with an appropriate drug with activity against anaerobes is recommended (see SmPC for the full indication).

It contains cefotaxime as the active substance and it is administered intravenously as 1g or 2 g powder for solution for injection or infusion.

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

Important risks of Cefotaxime hameln, together with measures to minimise such risks and the proposed studies for learning more about Cefotaxime hameln'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;
- 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed 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 Cefotaxime hameln are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administrated. 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 Cefotaxime hameln. 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

Not applicable – there are no safety concerns identified for medicinal product covered by this report.

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 Cefotaxime hameln.

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

There are no studies required for Cefotaxime hameln.