Part VI: Summary of the risk management plan

Summary of risk management plan for Ceftazidime hameln 500 mg powder for solution for injection, 1 g, 2 g, powder for solution for injection/infusion (Ceftazidime)

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

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

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

I. The medicine and what it is used for

Ceftazidime hameln is authorised for the treatment of the infections listed below in adults and children including neonates (from birth):

- Nosocomial pneumonia.
- Broncho-pulmonary infections in cystic fibrosis
- Bacterial meningitis
- Chronic suppurative otitis media
- Malignant otitis externa
- Complicated urinary tract infections
- Complicated skin and soft tissue infections
- Complicated intra-abdominal infections
- Bone and joint infections
- Peritonitis associated with dialysis in patients on continuous ambulatory peritoneal dialysis (CAPD).

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

Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Ceftazidime may be used in the peri-operative prophylaxis of urinary tract infections for patients undergoing trans-urethral resection of the prostate (TURP).

The selection of ceftazidime should take into account its antibacterial spectrum, which is mainly restricted to aerobic Gram-negative bacteria.

Ceftazidime should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum of activity (see SmPC for the full indications).

It contains ceftazidime as the active substance and it is given by intravenous injection or infusion, or by deep intramuscular injection.

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

Important risks Ceftazidime hameln, together with measures to minimise such risks and the proposed studies for learning more about Ceftazidime 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 Ceftazidime hameln 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 Ceftazidime 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

The safety information in the proposed Product Information is aligned to the reference medicinal product.

III.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 Ceftazidime hameln.

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

There are no studies required for Ceftazidime hameln.