Part VI: Summary of the risk management plan

Summary of risk management plan for Ceftriaxone hameln (ceftriaxone)

This is a summary of the risk management plan (RMP) for Ceftriaxone hameln. The RMP details important risks of Ceftriaxone hameln, and how more information will be obtained about Ceftriaxone hameln's risks and uncertainties (missing information).
Ceftriaxone hameln's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ceftriaxone hameln should be used.

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

I. The medicine and what it is used for

Ceftriaxone hameln is authorised for treatment of the following infections in adults and children including term neonates (from birth):

- Bacterial Meningitis
- Community acquired pneumonia
- Hospital acquired pneumonia
- Acute otitis media
- Intra-abdominal infections
- Complicated urinary tract infections (including pyelonephritis)
- Infections of bones and joints
- Complicated skin and soft tissue infections
- Gonorrhoea
- Syphilis
- Bacterial endocarditis

Ceftriaxone hameln may be used:

- For treatment of acute exacerbations of chronic obstructive pulmonary disease in adults
- For treatment of disseminated Lyme borreliosis (early (stage II) and late (stage III)) in adults and children including neonates from 15 days of age
- For Pre-operative prophylaxis of surgical site infections
- In the management of neutropenic patients with fever that is suspected to be due to a bacterial infection
- In the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Ceftriaxone hameln should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum.

Consideration should be given to official guidelines on the appropriate use of antibacterial agents (see SmPC for the full indication). It contains ceftriaxone sodium as the active substance and it is given intravenously and intramuscularly as 1 g, 2 g, powder for solution for injection/infusion.

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

Important risks of Ceftriaxone hameln, together with measures to minimise such risks and the proposed studies for learning more about Ceftriaxone 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 Product Information 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 Ceftriaxone hameln are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Ceftriaxone 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.

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 Ceftriaxone hameln.

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

There are no studies required for Ceftriaxone hameln.