Part VI: Summary of the risk management plan

Summary of risk management plan for

Ceftriaxone Kalceks 1 g powder for solution for injection/infusion
Ceftriaxone Kalceks 2 g powder for solution for infusion
(ceftriaxone)

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

Ceftriaxone Kalceks's summary of product characteristics (SPC) of Ceftriaxone Kalceks and its package leaflet give essential information to healthcare professionals and patients on how Ceftriaxone Kalceks should be used.

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

I. The medicine and what it is used for

Ceftriaxone Kalceks is authorised for the treatment of the 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 Kalceks 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.

It contains ceftriaxone as the active substance and it is given by intravenous or intramuscular route of administration in concentration of 1 g or 2 g per each vial.

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

Important risks of Ceftriaxone Kalceks, together with measures to minimise such risks and the proposed studies for learning more about risks of Ceftriaxone Kalceks, 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 SPC 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 Kalceks 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 Ceftriaxone Kalceks. 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).

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 medical 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 Kalceks.

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

There are no studies required for Ceftriaxone Kalceks.