PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

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

Important new concerns or changes to the current ones will be included in updates of Pivmecillinamhydrochlorid Karo Pharma's RMP.

I. The medicine and what it is used for

Pivmecillinamhydrochlorid Karo Pharma 400 mg film-coated tablets is indicated for adults in the treatment of acute uncomplicated cystitis caused by bacteria sensitive to mecillinam. It contains pivmecillinam hydrochloride as the active substance and it is administered orally.

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

Important risks of Pivmecillinamhydrochlorid Karo Pharma, together with measures to minimise such risks and the proposed studies for learning more about Pivmecillinamhydrochlorid Karo Pharma´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, including PSUR assessment 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 Pivmecillinamhydrochlorid Karo Pharma 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 Pivmecillinamhydrochlorid Karo Pharma. 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 important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The product information for Pivmecillinamhydrochlorid Karo Pharma contains information about its known risks. No risks have been identified as a safety concern for Pivmecillinamhydrochlorid Karo Pharma in the context of the Risk Management Plan.

II.C Post-authorisation development plan

There are no studies planned in the post-authorisation development plan for Pivmecillinamhydrochlorid Karo Pharma.

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligations for Pivmecillinamhydrochlorid Karo Pharma.

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

No studies are required for Pivmecillinamhydrochlorid Karo Pharma.