PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung (Piperacillin/Tazobactam)

This is a summary of the risk management plan (RMP) for Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung. The RMP details important risks of Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung , how these risks can be minimised, and how more information will be obtained about Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung's risks and uncertainties (missing information).

Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung should be used.

Important new concerns or changes to the current ones will be included in updates of Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung 's RMP.

I. The medicine and what it is used for

Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung is authorised for the treatment of the following infections in adults, adolescents and children over 2 years of age:

Adults and adolescents
- Severe pneumonia including hospital-acquired and ventilator-associated pneumonia

- Complicated urinary tract infections (including pyelonephritis)
- Complicated intra-abdominal infections
- Complicated skin and soft tissue infections (including diabetic foot infections)

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

Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung may be used in the management of neutropenic patients with fever suspected to be due to a bacterial infection. Use for bacteraemia due to ESBL producing E. coli and K. pneumoniae (ceftriaxone non-susceptible), is not recommended in adult patients. .

Children 2 to 12 years of age
- Complicated intra-abdominal infections

Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung may be used in the management of neutropenic children with fever suspected to be due to a bacterial infection.

See SmPC for the full indication.

It contains Piperacillin and Tazobactam as the active substances and is for intravenous use.

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

Important risks of Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung, together with measures to minimise such risks and the proposed studies for learning more about Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung 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 Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung 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 Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung . 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.

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 Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung.

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

There are no studies required for Piperacillin/Tazobactam Qilu 2 g/0,25 g Pulver zur Herstellung einer Infusionslösung and Piperacillin/Tazobactam Qilu 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung.