

## **7 Part VI: Summary of the risk management plan (RMP) Piperacillin/Tazobactam, 2 g/0.25 g and 4 g/0.5 g, Powder for Solution for Infusion**

This is a summary of the RMP for piperacillin/tazobactam, 2 g/0.25 g and 4 g/0.5 g, powder for solution for infusion. The RMP details important risks of piperacillin/tazobactam powder for solution for infusion, how these risks can be minimized, and how more information will be obtained about piperacillin/tazobactam powder for solution for infusion's risks and uncertainties (missing information).

Piperacillin/Tazobactam powder for solution for infusion's summaries of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how piperacillin/tazobactam powder for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of piperacillin/tazobactam powder for solution for infusion's RMP.

### **7.1 Part VI: I. The medicine and what it is used for**

Piperacillin belongs to the group of medicines known as “broad-spectrum penicillin antibiotics”. It can kill many kinds of bacteria. Tazobactam can prevent some resistant bacteria from surviving the effects of piperacillin. This means that when piperacillin and tazobactam are given together, more types of bacteria are killed.

Piperacillin/Tazobactam is used in adults and adolescents to treat bacterial infections, such as those affecting the lower respiratory tract (lungs), urinary tract (kidneys and bladder), abdomen, skin or blood. Piperacillin/Tazobactam may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Piperacillin/Tazobactam is used in children aged 2-12 years to treat infections of the abdomen such as appendicitis (condition in which appendix becomes inflamed (red or swollen) and painful), peritonitis (infection of the fluid and lining of the abdominal organs), and gallbladder (biliary) infections. Piperacillin/Tazobactam may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

In certain serious infections, doctor may consider using piperacillin/tazobactam in combination with other antibiotics.

It contains piperacillin/tazobactam as the active substance and is administered via parenteral route as powder for solution for infusion (2 g/0.25 g and 4 g/0.5 g).

### **7.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks**

Important risks of piperacillin/tazobactam powder for solution for infusion, together with measures to minimize such risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine’s packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessment (if applicable) so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance (PhV) activities*.

If important information that may affect the safe use of piperacillin/tazobactam powder for solution for infusion is not yet available, it is listed under ‘missing information’ below.

### 7.2.1 Part VI – II.A: List of important risks and missing information

Important risks of piperacillin/tazobactam powder for solution for infusion are risks that need special risk management activities to further investigate or minimize 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 powder for solution for infusion. 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).

**Table 7-1 List of important risks and missing information**

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

### 7.2.2 Part VI – II.B: Summary of important risks

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

### 7.2.3 Part VI – II.C: Post-authorization development plan

#### 7.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of piperacillin/tazobactam powder for solution for infusion.

### **7.2.3.2 II.C.2. Other studies in post-authorization development plan**

There are no studies required for piperacillin/tazobactam powder for solution for infusion.