V.3. Summary of risk minimisation measures

Table Part V.3 Summary table of pharmacovigilance activities and risk minimisation activities by safety concern

Safety concern	Risk minimisation measures	Pharmacovigilance activities
Important identified risks		
None proposed	None proposed	None proposed
Important potential risks:		
None proposed	None proposed	None proposed
Missing information:		
None proposed	None proposed	None proposed

Part VI: Summary of activities in the risk management plan by product:

This is a summary of the risk management plan (RMP) for Ampicillin sodium**.** The RMP details important risks of Ampicillin sodium, how these risks can be minimised, and uncertainties (missing information).
Ampicillin sodium summary of product characteristics (SPC) and its package leaflet give essential information to healthcare professionals and patients on how the drugs should be used.

I. The medicine and what it is used for

Ampicillin Antibiotice contains ampicillin sodium and is used for the treatment of bacterial infections. Ampicillin belongs to a group of medicines called beta-lactam antibiotics, broad spectrum penicillins.
Ampicillin Antibiotice is used to treat the following:
- Respiratory infections: epiglottitis, pharyngitis, tracheitis, bacterial pneumonia, acute bronchitis, exacerbation of chronic bronchitis;
- Otorhinolaryngological infections: otitis media, sinusitis;
- Urogenital tract infections: urinary infections (cystitis, pyelonephritis), gonococcal acute urethritis, gynecological infections (adnexitis, salpingitis, endometritis, parametritis), prostatitis;
- Digestive infections: bacterial gastroenteritis, dysentery, biliary infections, as alternative therapy in typhoid and paratyphoid fever;
- Other infections with sensitive germs: septicaemia, bacterial endocarditis, bacterial meningitis, leptospirosis, listeriosis, peritonitis.

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

Important risks of Ampicillin Antibiotice powder for solution for injection/infusion (500 mg; 1 g; 2 g) together with measures to minimise such risks, are outlined below.

Measures to minimise the risks identified are:
- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet (PL) and SPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging
- The medicine's legal status- Prescription product.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, routine pharmacovigilance activities including adverse reactions reporting, PSUR, medical literature monitoring, and other activities as required under EU legislation, are made.

No additional risk minimisation measures are proposed.

No missing information is identified at this date for ampicillin sodium.

II. A. List of important risks and missing information

Important risks of ampicillin sodium 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 ampicillin sodium. 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 off-label use (including use in paediatrics).

Summary of safety concerns	
Important identified risks	None proposed.
Important potential risks	None proposed.
Missing information	None proposed.

II.B. Summary of important risks

The safety information in the Product Information and in the Summary of the Product Characteristics for ampicillin sodium is aligned to the reference medicinal product and based on a well-known safety profile of the medicine. The MAH will perform the required pharmacovigilance activities and interventions detailed in the Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

II. C. Post- authorisation development plan

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

Not applicable.

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

Not applicable.