Summary of risk management plan for Ampitar (*Ampicillin*)

This is a summary of the risk management plan (RMP) for Ampitar 1 g powder for solution for injection/infusion and Ampitar 2 g powder for solution for injection/infusion (hereinafter: Ampitar). The RMP details important risks of Ampitar and how more information will be obtained about Ampitar risks and uncertainties (missing information).

The summary of product characteristics (SmPC) of Ampitar and its package leaflet give essential information to healthcare professionals and patients on how Ampitar should be used.

Important new concerns or changes to the current ones will be included in updates of Ampitar RMP.

I. The medicine and what it is used for

Ampitar is indicated for the treatment of the following infections in adults and children (see section 5.1):

- Acute exacerbation of chronic bronchitis
- Urinary tract infection
- Bacterial meningitis
- Community-acquired pneumonia when penicillin G has not given the desired effect or is unsuitable for other reasons
- Intra-abdominal infections
- Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above
- Treatment and prophylaxis of endocarditis.

It contains ampicillin (as ampicillin sodium) as the active substance and the ready-for-use solution is administered deeply intramuscularly or intravenously.

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

Important risks of Ampitar, together with measures to minimise such risks and the proposed studies for learning more about Ampitar'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 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 Ampitar 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 the medicinal product Ampitar. 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 medicinal product.

II.C Post-authorisation development plan

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

There are no studies that are conditions of the marketing authorisation or specific obligation of Ampitar.

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

There are no studies required for Ampitar.

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