

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Ampicillin STADA Nordic (ampicillin)

This is a summary of the risk management plan (RMP) for Ampicillin STADA Nordic. The RMP details important risks of Ampicillin STADA Nordic, how these risks can be minimised, and how more information will be obtained about Ampicillin STADA Nordic's risks and uncertainties (missing information).

Ampicillin STADA Nordic's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ampicillin STADA Nordic should be used.

Important new concerns or changes to the current ones will be included in updates of Ampicillin STADA Nordic's RMP.

#### I. The medicine and what it is used for

Ampicillin STADA Nordic is authorised for the initiation of therapy of a wide range of infections caused by susceptibility tested strains of both gram-positive and gram-negative bacteria, or for the therapy of severe infections, particularly in patients in whom oral administration is not feasible; for the treatment of bacteraemia; and for perioperative infection prophylaxis (see SmPC for the full indication). It contains ampicillin as the active substance and it is given i.v., i.m. or as an infusion.

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

Important risks of Ampicillin STADA Nordic, together with measures to minimise such risks and the proposed studies for learning more about Ampicillin STADA Nordic'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 Ampicillin STADA Nordic 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 STADA Nordic. 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);

<b>List of important risks and missing information</b>	
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 Ampicillin STADA Nordic.

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

There are no studies required for Ampicillin STADA Nordic.